



# Safe Supplies: Completing the Picture

Annual review from the NHS Blood and Transplant/PHE Epidemiology Unit, 2012



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## **Foreword**

I am pleased to introduce the 2012 annual review produced by the joint NHSBT/PHE Epidemiology Unit.

As you are aware the last year has seen a number of changes across health and social care within England, one of these being the formation of Public Health England (PHE). The joint unit is now hosted by NHSBT Colindale and the Centre for Infectious Disease Surveillance and Control at PHE.

This year's report includes reports of infections in both organ donors, and cornea donors tested by NHSBT. This could not have been possible without input from clinical and scientific colleagues. During the next year it is planned to develop these surveillance systems further.

During 2012 the team have contributed to a number of infectious disease risk assessments for both SaBTO and JPAC, and continued to contribute to non-infectious disease risk assessments relating to donor selection criteria.

This is the first report since the change to the MSM donor selection criteria for blood donors and although it is too soon to fully assess the impact of this change, there does not appear to have been any increase in window-period infections; indeed there has been a decrease in the overall rates of infectious markers since 2011. However, there continues to be a small number of donors who do not comply with the donor selection criteria for a number of reasons including assessing their own risk as low. During 2013 the unit together with colleagues within NHSBT, the three other UK blood services and PHE will launch the UK blood donor survey which aims to gather information on the characteristics of both new and regular donors, including information on their lifestyle and behaviours which may impact on donor selection. This will also include feedback on donors' ease of understanding of the Donor Healthcheck Questionnaire.

I hope you find this year's report interesting; the epidemiology team are always happy to respond to specific requests for data or further information.

Safe Supplies: Completing the Picture

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## Contents

About Public Health England	2
Acknowledgements	3
Foreword	5
Contents	7
Executive summary	8
Recent publications	12
1.0 Introduction	13
2.0 Blood donor surveillance	15
3.0 The risk estimates in the UK, 2010-2012	30
4.0 Transfusion transmitted infection	32
5.0 Bacterial screening	36
6.0 PHE Blood Borne Virus Unit	40
7.0 Tissue and cord blood donors	43
8.0 Deceased solid organ donor surveillance	52
9.0 Surveillance of emerging infections	57
10.0 Glossary of abbreviations	59
11 0 References	61

## **Executive summary**

#### **Blood donors**

During 2012, just over 2 million donations were tested by NHSBT compared with 2.4 million across the UK. The majority of blood donors in England and north Wales were white (91%), female (54%) and over half were aged 45 years and older. Of the active whole blood donors 15% were classified as new i.e. had not given blood in the previous two years. Among those donors who described themselves as black African 43% (2,213) were new donors, compared with 37% of Asian donors and 14% of white donors.

As in previous years a small number of donors were found to be positive for markers of current or past infection. In the UK, 241 donations tested positive for a marker of infection, an overall rate of 9.9 donations per 100,000. This is a decrease in the overall rate of 18% since 2011. As in previous years the majority of donors contributing to this rate were new donors (83%).

Markers of HBV, HCV and treponemal antibodies were the most commonly identified markers. Seventy one donations were positive for HBV infection, 68 identified as chronic HBV infections. Of these 68 chronic infections four were defined as occult HBV. The remaining three donations were from donors who had an acute, recent HBV infection, most likely acquired through sexual contact; all were white and 2/3 born in the UK.

HCV markers were detected in 70 donations made in the UK, Republic of Ireland, Channel Islands and Isle of Man; 16 (23%) had antibodies only, suggestive of a cleared infection. The donors were mainly male (64%), white (81%) and born in the UK (57%). This group of donors were most likely to have no risk reported (34%), but where known, 28% disclosed current or previous use of injecting drugs.

Treponemal antibodies were reported for 79 donations, one given by a donor with a history of yaws. Of these (excluding Scotland), 20 were acute or recent syphilis infections suggesting recent high-risk sexual behaviour. Of the positive donors 51 disclosed a risk, 42 relating to sex between men and women (SBMW) and eight were men who have sex with men (MSM).

HIV continued to be detected in a small number of donors, representing 7% of all positive donations. The majority of positive donors were white (87%), born in the UK (86%) and male (75%). Risk factor information was collected from 13 donors, of these eight disclosed sex between men and women (SBMW) as a risk, 4/13 were MSM and one was born in an endemic country with no other risk factors.

HTLV infection was identified in ten new donors, none of these donors were aware of their infection. HTLV positive donors are invited to join the HTLV register which was set up in collaboration with Imperial College and PHE after the introduction of HTLV testing in 2002. The register aims to follow a cohort of asymptomatic individuals with HTLV over a number of years collecting information on self-reported health. This is one of only two such registries still recruiting in the world, the other based in Brazil.

Additional testing of components for anti-HBc, malarial antibodies, antibodies to *T. cruzi* and West Nile virus NAT by NHSBT resulted in an additional 99,840 donations being available for issue where other mandated tests were negative.

Using the risk information disclosed by donors during the post-test discussion it was possible to ascertain compliance with donor selection for donors in the UK (excluding Scotland because information on reasons for non-disclosure at the time of donation is not currently provided). It was found that 34/223 infected donors were non-compliant (15%); an additional three Scottish donors were also reported as non-compliant. Of the 34 donors 26 gave a reason why they were non-compliant. The majority of these donors were IDU (13), ten were MSM who had had sexual contact with a man in the 12 months prior to donation and four were already aware of their infection. During 2012, 15 donors disclosed that they were past or current MSM, of these four were compliant with current selection criteria. The main reason for non-compliance was the donor assessing their own risk as low.

The current estimated risk of a potentially infectious donation being issued remains low. The estimated risk was modelled using observed UK data for 2010-2012 and data on the window period of current tests. As in previous years HBV has the greatest risk of transmission due to the longer window period. The current risks are estimated for HBV as one per 1.27 million or 1-2 HBV misses per year, for HIV as one per 7.04 million or one HIV miss every 2-3 years and for HCV as one per 29 million or one HCV miss every 12 years. These may be overestimates because of a large amount of uncertainty in the data used. A HBV transmission which was reported in 2011 was confirmed in 2012; this was the first confirmed, reported HBV incident since 2005. During 2012, two further TTIs were confirmed, a case of parvovirus B19 virus and a hepatitis E virus incident; neither of these viruses are part of routine screening. In both cases the donor was asymptomatic. No bacterial TTIs have been reported and confirmed since 2009. During 2012, 237,212 apheresis platelets and 40,863 pooled platelets were screened for the presence of bacteria. All platelets that were initially reactive were further investigated. Growth, either confirmed positive or indeterminate positive, was identified from 94 (0.04%) and 49 (0.12%) of screened apheresis and pooled platelets, respectively. Bacterial screening helped to prevent the transfusion of packs from over ten donations containing potentially pathogenic bacteria.

#### **Tissue donors**

Data on infections in cornea donors tested by NHSBT is included in the review for the first time. Compared to blood donations, the number of tissue, cornea and cord blood donors is relatively small but in the case of a deceased tissue donor they may donate tissues for use in many patients. The surveillance programme for surgical bone donors began in 2001; since then 42,630 donors have been tested by NHSBT. During 2012, 3,543 donors were tested and one donor was HTLV positive, the first surgical bone donor to test positive since screening began. In addition four donors had evidence of past treponemal infection. Fewer donors are tested in Scotland and Northern Ireland but in 2012 there were 12 and two donors with markers of infection, respectively.

A total of 560 deceased donors were tested by NHSBT in 2012. Only one donor, who was also a cornea donor, tested positive; this donor was HIV positive, the second HIV positive deceased tissue donor since surveillance began. Of the cornea donors tested by NHSBT (2,924), one had chronic HBV, one was HTLV positive, one (also reported as a deceased donor above) was HIV positive and eight had treponemal antibodies. Further work is required to identify those cornea donors who also donate tissues and/or organs.

Information on screening of cord blood donors is available from NHSBT and NIBTS; no donors have tested positive in Northern Ireland since screening began in 2007. NHSBT collect cord blood donations from hospitals in the London area. All mothers should be offered testing for HBV, HIV and syphilis as part of the antenatal screening programme therefore we would not expect to find any donor positive for these infections. During 2012, 2/2,449 donors had low level reactivity to treponemal antibodies reflecting a long-past syphilis infection, however, this is unlikely to represent an antenatal screening miss but rather reflect the sensitivity of current cord blood donor testing. In addition, 40/928 donors tested had malarial antibodies reflecting the diversity of this group of donors.

#### **Organ donors**

Infection surveillance data are presented for proceeding organ donors for the first time. Unlike tissue donors organ donors are tested by the local hospital laboratory rather than NHSBT laboratories. Donors are routinely tested for markers of HIV, HBV, HCV, HTLV, cytomegalovirus (CMV), Epstein-Barr virus (EBV), treponema and *Toxoplasma gondii*. As organ transplant is a life saving procedure organs from donors with markers of infections will be offered and transplanted with appropriate prophylaxis given to the recipient. In 2012, 3,945 organs were donated; 3,377 organs from 1,078 deceased solid organ donors were transplanted. The positivity rate for proceeding donors varied by infection. EBV and CMV were detected in 86% and 52%, respectively, of donors for whom a test result was available. Initially reactive screening results were also obtained for the following: HBV core antibodies, 30 donors; HBV surface antigen, two donors; HCV antibodies, five donors. No reactivity for HIV antigen/antibodies was seen.

#### **Horizon scanning**

The unit together with colleagues in PHE and the wider public health community continue to monitor emerging infections across the world which may be of significance to the blood services. WNV was of concern in 2012 as it continued to spread across Europe leading to the 28 day deferral for blood donors returning from a WNV area being replaced by WNV NAT testing. Locally acquired malaria continued to circulate in Greece and this continues to be monitored. A new SARS-like virus was reported in the Middle East during autumn 2012, this respiratory virus is known as MERS-CoV. To date there appears to be limited person-to-person spread; as of August 2013 WHO reported 94 laboratory confirmed cases including 46 deaths.

#### Joint working

We continue to work with our colleagues in the Blood Borne Virus Unit (BBVU) at PHE to gain better insight into infection in our donors, particularly by combining genotyping data and donor characteristics to gain a better understanding of possible undisclosed risk factors. The BBVU also works with the NHSBT Transfusion Microbiology team to investigate the incidence of hepatitis E in blood donors and the potential for transmission to recipients. These molecular science and epidemiological data continue to contribute to policy both internally and externally.

## Recent publications

- 1. Brown CS, Chand MA, Hoffman P, Woodford N, Livermore DM, Brailsford S, Gharbia S, Small N, Billingham E, Zambon M, Grant K. United Kingdom incident response team (2012) Possible contamination of organ preservation fluid with *Bacillus cereus*: the United Kingdom response. *Euro. Surveill.* **17**(18):pii=20165.
- 2. Byrne L, Brant L, Reynolds C, Ramsay M (2012) Seroprevalence of low rubella IgG antibody levels among antenatal women in England tested by NHS Blood and Transplant: 2004-2009. Is rubella susceptibility increasing? *Vaccine* **30**:161-167.
- 3. 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 Sang.***105**:85-88.
- 4. Garson JA, Patel P, McDonald C, Ball J, Rosenberg G, Tettmar KI, Brailsford SR, Pitt T, Tedder RS (2013) 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* May 23. doi: 10.1111/trf.12256. [Epub ahead of print]
- 5. 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* Feb 5. doi: 10.1111/trf.12105. [Epub ahead of print]
- Parry RP, Tettmar KI, Hoschler K, Brailsford SR, Samuel D, Ashford M, Maclennan S, Williamson LM, Tedder RS (2012) Strategies for screening blood donors to source convalescent H1N1v plasma for intervention therapy. *Vox* Sang.103:107-112.
- 7. Rosenberg GK, Lattimore S, Brailsford SR, Hewitt PE, Tettmar KI, Kitchen AD, Ijaz S, Tedder RS (2012) The diversity of chronic hepatitis B virus infections within blood donors in England and North Wales 2005 through 2010.

  \*\*Transfusion\*\* Dec 7. doi: 10.1111/trf.12003. [Epub ahead of print].

## 1.0 Introduction

The title of this year's annual review, "Safe Supplies: Completing the Picture", reflects the expansion of the surveillance programme to include two new areas: markers of infection in both organ donors and donors of corneas. Working with colleagues within ODT and Tissue Services, we are able, for the first time, to report numbers and rates of markers of infection in both organ donors and cornea donors (screened and confirmed by NTMRL). In addition to our surveillance work we have also provided data and expertise to the SaBTO subgroup, reviewing the MSM donor selection criteria for tissue and cell donation.

We also provided epidemiology assistance to two JPAC committees: the Standing Advisory Committee on the Care and Selection of Donors (SACCSD) and the Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI). For SACCSD we have worked closely with colleagues at the South West Public Health Observatory (now part of PHE) and the National Cancer Intelligence Network to use information held within the National Cancer Data Repository to estimate the likely impact of a change in the deferral criteria for individuals with a past history of cancer. We have calculated the impact of this change for the English blood service in terms of the potential increase in the number of newly eligible donors and their donations. Whereas for SACTTI we continue to develop the risk estimate model including using a simulation approach to model the risk of an infectious donation being available for issue. We have contributed to a European review of a new model, EUFRAT, to assess the risk to the blood supply of outbreaks of infectious disease.

With colleagues in the other UK blood services we have also been developing a project to look at donor understanding of the donor health check procedure and compliance to the donor selection guidelines with an emphasis on infectious disease risks. A focus group and pilot survey have been carried out and the main survey in collaboration with PHE and the four UK blood services will start in the autumn of 2013. It is hoped that this project will provide useful data on our donors' health, lifestyle and understanding of why donor selection criteria are so important.

Over the last 12 months the team accepted invitations to speak at the Federation of Infection Societies, the Health Protection Agency conference and BBTS and presented at a number of national and international conferences. We have also continued to publish in peer-reviewed journals; a list of our recent publications is shown on the previous page.

In addition to the information presented in this report, surveillance data is regularly updated on the internet (http://www.hpa.org.uk/infections/topics\_az/BIBD). The following additional documents are also available:

Supplementary data tables and figures: Data tables not presented in this report are available in PDF format from our web pages.

Data sources and methods: Outlines the sources and methods of data collection for the surveillance schemes operated by the NHSBT/PHE Epidemiology Unit.

Please contact epidemiology@nhsbt.nhs.uk if you require other data that is not available online.

## 2.0 Blood donor surveillance

#### **Key findings**

- during 2012, the rate of markers of HBV, HCV, HIV, HTLV and treponema infection among UK blood donors was low with 9.9 donations confirmed positive per 100,000 tested. This is an 18% decrease in overall rate compared with 2011
- testing in the UK, Channel Islands and the Republic of Ireland detected 246 donations with confirmed markers of HBV (71), HCV (70), HIV (16), HTLV (10) and treponema (79). As in 2011, markers of HBV, HCV and treponema predominated
- during 2012, as in earlier years, the rate of infection among new UK donors far exceeded that of repeat donors (104 and 1.8 per 100,000 donations, respectively)
- 68 of the HBV infected donors had chronic infections, of which four were classified as occult. Three donors had acute infections
- where known, most of the UK donors (61.5%; 8/13) with markers of HIV reported sex between men and women as the likely source of their HIV. Fewer donors had markers of HIV (15) in 2012 than 2011 (23). In 2012, the proportion among repeat donors was lower than in 2011 (46.7% and 56.5%, respectively)
- where known, 34 infected donors (15%; 34/223) were non-compliant with donor selection guidelines in 2012 and should not have donated blood. Ten (29%; 10/34) non-compliant donors reported sex between men
- in 2012, additional testing was carried out on 101,291 donations, 4.9% of all donations tested. Of these, 99,840 were non-reactive and available for issue if they were also non-reactive to the mandatory markers of infection

#### 2.1. Donor Insight England and north Wales

In 2012, in England and north Wales, whole blood and component donations were made by 1,036,428 and 15,053 donors, respectively (Table 2.1). A significantly higher proportion of females donated blood than males (53.8% vs. 46.2%; p<0.001), with half of all donors (51.7%) aged over 45, and mainly of white ethnicity (91.3%). 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 13.8% 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 10.97 in London to 24.54 in the East of England. Among whole blood donors, 14.9% (154,353) were new donors, over half (56.9%) 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 2.1, Figure 2.1). New donors were seen among all ethnic groups, comprising 13.9% of all white donors, 37.2% of Asian (Indian, Pakistani and Bangladeshi) donors, and 42.9% of black African donors. New blood donors were drawn from all regions in England. The highest proportion of new donors in each region was resident in London, where 21.6% of all London blood donors were new donors.

Table 2.1: Summary of demographic characteristics of whole blood donors in England and north Wales, 2012<sup>1</sup>

	All don	ors	Ne	w donors	5
	n	%	n	%	% <sup>2</sup>
Sex					
Male	470 704	40.0	00.000	40.0	40.0
	478,701	46.2	66,382	43.0	13.9
Female	557,727	53.8	87,971	57.0	15.8
Age group					
17-24	137,693	13.3	55,772	36.1	40.5
25-34	164,338	15.9	39,261	25.4	23.9
35-44	197,910	19.1	28,283	18.3	14.3
45-54	260,544	25.1	21,138	13.7	8.1
55+	275,943	26.6	9,899	6.4	3.6
Ethnic background					
Asian	18,190	1.8	6,770	4.4	37.2
White	946,685	91.3	131,367	85.1	13.9
Black African	2,213	0.2	950	0.6	42.9
Black Caribbean	3,339	0.3	720	0.5	21.6
Chinese	2,427	0.2	829	0.5	34.2
Mixed	9,322	0.9	2,821	1.8	30.3
Other/Unknown	54,252	5.2	10,896	7.1	20.1
Region of residence					
East Midlands	101,956	9.8	13,666	8.9	13.4
East of England	143,491	13.8	19,757	12.8	13.8
London	89,749	8.7	19,390	12.6	21.6
North East	50,169	4.8	7,175	4.6	14.3
North West	108,362	10.5	17,625	11.4	16.3
South Central	101,019	9.7	14,717	9.5	14.6
South East Coast	98,329	9.5	12,899	8.4	13.1
South West	123,799	11.9	16,918	11.0	13.7
West Midlands	101,189	9.8	14,510	9.4	14.3
Yorkshire and Humber	105,785	10.2	15,570	10.1	14.7
North Wales	11,713	1.1	1,816	1.2	15.5
Outside England <sup>3</sup>	867	0.1	310	0.2	35.8
Total	1,036,428	-	154,353	-	-

<sup>1.</sup> Number of new donors reported here differ slightly from donations from new donors in Table 2.2 because different data sources were used (see "Data Sources and Methods" document for details).

<sup>2.</sup> Proportion of new donors within each category.

<sup>3.</sup> The high proportion of new donors resident outside England is likely to be due to individuals who had previously donated elsewhere, either elsewhere in the UK or overseas.

100% 90% 80% 70% 60% **≤** 55± ■ 45-54 50% **■** 35-44 40% ■ 25-34 **■** 17-24 30% 20% 10% 0% Repeat New Donor type

Figure 2.1: Age groups of new and repeat whole blood donors in England and north Wales, 2012

#### 2.2. Overview of 2012

In the UK, during 2012, a total of 241 blood donations were confirmed positive for markers of HBV, HCV, HIV, HTLV or treponema among just over 2.4 million blood donations tested (Table 2.2). This approximates to a rate of 9.9 positive donations per 100,000. In both England and in the UK overall, markers of HBV, HCV and treponema predominated (71, 69 and 76 donations in the UK, respectively). Over four-fifths (83%; 200/241) of donations confirmed positive for markers of *any* infection were collected from new donors. The rate of detection of viral infection (per 100,000 donors) in 2012 in new and repeat donors by gender and age group is shown in Figure 2.2.

Table 2.2: The number and rate of markers of HBV, HCV, HIV, HTLV and treponemal antibodies<sup>1</sup> identified among blood donations made at blood centres by new and repeat donors<sup>2</sup> and country where donation was made, 2012

	D	onations tes	ted		HBV			HCV			HIV			HTLV			ponema tibodies			Total	
Country of blood centre	New	Rpt	All	New	Rpt	All	New	Rpt	All	New	Rpt	All	New	Rpt	All	New	Rpt	All	New	Rpt	All
England	155,692	1,887,787	2,043,479	55	5	60	52	5	57	4	5	9	8	1	9	46	15	61	165	31	196
Rate <sup>3</sup>				35.3	0.3	2.9	33.4	0.3	2.8	2.6	0.3	0.4	5.1	0.05	0.4	29.5	0.8	3.0	106.0	1.6	9.6
Wales	7,954	86,314	94,268	3	0	3	6	0	6	2	1	3	1	0	1	3	1	4	15	2	17
Rate <sup>3</sup>				37.7	0.0	3.2	75.4	0.0	6.4	25.1	1.2	3.2	12.6	0.00	1.1	37.7	1.2	4.2	188.6	2.3	18.0
Northern Ireland	6,982	57,108	64,090	1	0	1	1	0	1	1	0	1	0	0	0	0	2	2	3	2	5
Rate <sup>3</sup>				14.3	0.0	1.6	14.3	0.0	1.6	14.3	0.0	1.6	0.0	0.00	0.0	0.0	3.5	3.1	43.0	3.5	7.8
Scotland	22,006	202,133	224,139	6	1	7	5	0	5	1	1	2	0	0	0	5	4	9	17	6	23
Rate <sup>3</sup>				27.3	0.5	3.1	22.7	0.0	2.2	4.5	0.5	0.9	0.0	0.00	0.0	22.7	2.0	4.0	77.3	3.0	10.3
Total UK	192,634	2,233,342	2,425,976	65	6	71	64	5	69	8	7	15	9	1	10	54	22	76	200	41	241
Rate <sup>3</sup>				33.7	0.3	2.9	33.2	0.2	2.8	4.2	0.3	0.6	4.7	0.04	0.4	28.0	1.0	3.1	103.8	1.8	9.9
Republic of Ireland	10,297	140,185	150,482	0	0	0	0	1	1	1	0	1	0	0	0	1	2	3	2	3	5
Rate <sup>3</sup>				0.0	0.0	0.0	0.0	0.7	0.7	9.7	0.0	0.7	0.0	0.00	0.0	9.7	1.4	2.0	19.4	2.1	3.3
Channel Isles & I. of Man	710	5,461	6,171	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rate <sup>3</sup>				0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.00	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total	203,641	2,378,988	2,582,629	65	6	71	64	6	70	9	7	16	9	1	10	55	24	79	202	44	246
Rate <sup>3</sup>				31.9	0.3	2.7	31.4	0.3	2.7	4.4	0.3	0.6	4.4	0.04	0.4	27.0	1.0	3.1	99.2	1.8	9.5

<sup>1.</sup> Treponemal antibody testing detects both recent and past syphilis infection caused by the bacterium *T. pallidum*. It also detects 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.

<sup>2.</sup> New and repeat donors classified according to records available to the blood centre and therefore new donors will include lapsed donors for all countries except Scotland. Numbers of donations reported here differ slightly from new donors in Table 2.1 because different data sources were used (see 'Data Sources and Methods' document for details).

<sup>3.</sup> Rate per 100,000 donations.

0

17-24

25-34

35-44

Age group

45 and over

**New donors** Repeat donors 180 4 160 Rate per 100,000 donations Rate per 100,000 donations ■Rate in males 140 Rate in females 3 120 100 2 80 60 1 40 20

Figure 2.2: The estimated rate of viral infection in new and repeat donors by gender and age group: UK, Channel Islands and ROI, 2012

Note: The rate per 100,000 donations is an estimate only as denominator data for England and north Wales was applied to the UK, Channel Islands and Republic of Ireland.

n

17-24

25-34

35-44

Age group

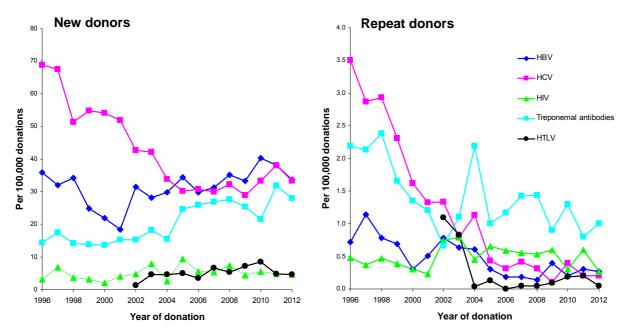
45 and over

Between 2011 and 2012, the number of confirmed markers of any infection among UK blood donations fell from 295 to 241, with an 18% reduction in rate per 100,000 donations. Between 1996 and 2012, the detection of confirmed markers of all infections fell, with the decline being most marked in repeat donors (Figure 2.3). 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).

During 2012, HBV was detected at a rate of 2.9 per 100,000 donations in the UK overall. As in previous years, new donors accounted for most (92%; 65/71) donations confirmed positive for HBV. Acute HBV was identified among three donors who had all donated previously. Chronic HBV was identified in 68 donors, four of these were occult infections that were initially identified on the basis of a positive NAT screening result in the absence of hepatitis B surface antigen (HBsAg). On confirmatory testing occult HBV infection was identified. As appropriate, testing of archive samples and a further donor sample was carried out to confirm the status. In each case, both the local health protection team and the donor's GP were informed of these results.

During 2012, 15 donations made in the UK were positive for markers of HIV, a rate of 0.6 per 100,000 donations. In the UK, new donors accounted for 53% (8/15) of donations confirmed positive for markers of HIV, however, the rate of markers of HIV infection among new donors was 16 times that of repeat donors.

Figure 2.3: The rate<sup>1</sup> of markers of HBV, HCV, HIV, HTLV and treponemal antibodies in blood donations from new and repeat donors made at blood centres in the UK, 1996-2012 (note different scales)



1. Rate per 100,000 donations.

#### 2.3. Infected blood donors in 2012

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, for example, injecting drug user (IDU), then MSM, followed by sex between men and women (SBMW) etc. A summary of this data is presented in Table 2.3. In the UK, white males aged between 30 and 40 and born in the UK predominated among infected donors, with heterogeneity in these characteristics between infections. More detailed information about all infected donors is published in the "Supplementary Data Tables and Figures" document.

#### **HBV**

In 2012, HBV infections identified in the UK, Channel Isles, Isle of Man and the ROI, accounted for over a quarter (29%; 71/246) of all infected donors. Clinicians reported 96% (68/71) of infections as chronic; the majority (96%; 65/68) were newly tested for HBsAg. The characteristics of HBV infected donors shown in Table 2.3 therefore represent those of donors with chronic HBV infection. Overall, HBV infected donors were similar in terms of age and sex to HCV and HIV infected donors but differed in terms of ethnicity and country of birth.

Table 2.3: Summary of characteristics of infected blood donors in the UK, the Channel Islands and Republic of Ireland, 2012

	нву	HCV	HIV	HTLV	Treponemal antibodies
No. of donors with marker(s) of infection	71	70	16	10	79
Seroconversions <sup>1</sup>	3	5	6	0	-
% Male (no. donors)	67.6 (48)	64.3 (45)	75.0 (12)	20.0 (2)	68.4 (54)
Mean age	33.7	38.5	31.5	39.8	41.6
% White, where known <sup>2</sup> (no. donors)	38.0 (27)	81.2 (56)	86.7 (13)	40.0 (4)	74.0 (57)
% Born UK or ROI, where known <sup>3</sup> (no. donors)	20.6 (13)	56.9 (33)	85.7 (12)	22.2 (2)	70.0 (42)
Main probable exposure, where known (%; no. donors)	Infection associated with an endemic country <sup>5</sup> (52.9%; 27)	Injecting drug user (IDU) (28.3%; 13)	Sex between men and women (61.5%; 8)	Infection associated with an endemic country <sup>5</sup> (44.4%; 4)	Sex between men and women (82.4%; 42)
Second most common probable exposure, where known (%; no. donors)	Sex between men and women (13.7%; 7)	Tattooing/body and ear piercing/ acupuncture (28.3%; 13)	Sex between men (30.8%; 4)	Born in an endemic country & heterosexual partner from an endemic country (33.3%; 3)	Sex between men (15.7%; 8)
% Probable exposure not known <sup>4</sup> (no. donors)	28.2 (8)	34.3 (24)	18.8 (3)	10.0 (1)	35.4 (28)

<sup>1.</sup> Seroconversions for viral infections were counted in donors who had a previous negative donation <3 years ago. One HCV infection and two HIV infections in lapsed donors whose previous negative donations were >3 years ago are excluded from this table.

For HBV infected donors, where known, two-fifths were of white ethnicity (38%; 27/71). One-fifth was born in the UK compared to over half (57%, 33/58) of HCV and over four-fifths (86%, 12/14) of HIV infected donors. For at least half (53%, 27/51) of HBV infected donors their infection was probably related to being born in or to a mother from a country with a high prevalence of HBV or having a sibling with the infection.

<sup>2.</sup> Ethnicity was not known for 1.6% of donors.

<sup>3.</sup> Country of birth was not known for 11.3% of HBV, 17.1% of HCV, 12.5% of HIV, 10.0% of HTLV positive donors and 24.1% of donors testing positive for treponemal antibodies.

<sup>4.</sup> Includes incomplete follow-up and no identified exposure despite donor interview.

<sup>5.</sup> 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.

Four donors had occult HBV infections. Three were repeat donors who were previously HBV DNA screen negative; this was probably due to a low fluctuating viral load which was below the cut-off level for a positive screen at their previous donation. HBV NAT screening is not mandatory but a consequence of the Triplex NAT test rolled out in the UK between April 2009 and March 2010 and has proved useful in detecting both early and late acute HBV infections and occult HBV. These chronic occult infections are categorised by additional testing for HBV markers including anti-HBc and the history supplied by the donor. Two occult HBV infections were identified in 2009, none in 2010 and five in 2011.

In contrast to chronic infections, all three donors with acute infections were of white ethnicity and two of these donors were born in the UK. All acute HBV infections were in previously tested donors, and all were classified as seroconverters (with a previous negative donation within three years). Where known (2), one donor probably acquired their infection as a result of sex between men and one from SBMW with a "high risk" partner.

#### **HCV**

In 2012, HCV infections identified in the UK, Channel Isles, Isle of Man and the ROI accounted for 28% (70/246) of all confirmed infections but 16 were likely to be cleared infections. Where known, donors with markers of HCV infection were most likely to be white (81%; 56/69), male (64%; 45/70), and slightly more likely to born in the UK or ROI (57%, 33/58) than overseas. A likely source of infection was not identified for 34% of HCV infected donors, a rate comparable to 2011 (30.2%) but higher than for previous years. Where known, the main probable exposure to HCV infection was among people who had a history of injecting drug use (28%, 13/46). Thirteen donors (28%; 13/46) possibly acquired their infection through procedures including tattooing, body/ear piercing or acupuncture (28%; 13/46). Six donors probably acquired their infection as a result of SBMW (13%; 6/46) and one had engaged in sex between men but probably became infected as a result of injecting drug use (2%; 1/46). Five donors (11%; 5/46) had possible contact with HCV infected blood or tissue. Intra-nasal drug use was the most likely exposure disclosed for four donors (9%; 4/46). A further three donors had no specific reported risk, but possibly became infected due to an association with a country with higher HCV prevalence than the UK (7%; 3/46). One donor (2%; 1/46) reported family or household contact as the most likely source of infection.

Six (9%; 6/70) previously tested HCV infected donors tested negative at the previous donation; five of these donors had seroconverted within the last three years. Four of the six were male, where ethnicity was known (5) all were white and, where country of birth was known (5), all were born in the UK or ROI. Where known (3), these donors probably acquired their infection as a result of IDU, sex between men and SBMW with a "high risk" partner. One HCV infected donor was initially detected by a positive NAT at

screening (anti-HCV screen negative) and this was probably a recent infection acquired as a result of SBMW with a partner with a history of IDU.

#### HIV

In 2012, HIV infections identified in the UK, Channel Isles, Isle of Man and the ROI accounted for 7% (16/246) of all infected donors. Where known, the majority of HIV infected donors were male (75%; 12/16), of white ethnicity (87%; 13/15) and born in the UK or ROI (86%; 12/14). The mean age was 32 years (range 20-58 years). Of the donors with identified risk factors, eight donors (62%; 8/13) probably acquired their infection as a result of SBMW. Two of these (25%; 2/8) had partners who were categorised as 'high risk' (IDU or sex in Africa) and six (75%; 6/8) where the donor did not disclose a risk related to their partner which would have resulted in a deferral. Four donors (31%; 4/13) probably acquired their HIV infection via sex between men. One HIV infected donor (8%; 1/13) was born in Africa and did not disclose any history of sexual contact or drug use.

Eight HIV infected donors (50%; 8/16) tested negative at the previous donation, six were classified as seroconverters within the last three years. Six (75%; 6/8) were male, all were of white British ethnicity and, where known (7), were born in the UK. Where reported, the source of infection for four donors was probably through SBMW (67%; 4/6), none of whom reported a partner known to have "high risk" behaviours, although three donors reported a new partner within the last 12 months. The remaining two (33%, 2/6) were MSM. These two donors were non-compliant with the donor selection guidelines (DSG) since their last sex with another man was reported to be within the last year (one within the last four months).

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 the National Transfusion Microbiology Reference Laboratory (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. In 2012, look-back to MRPND was undertaken for seven seroconverters; the results of two of these investigations are outstanding. Look-back to MRPND was not carried out for three seroconverters for reasons including a history and avidity result suggestive of a recently acquired infection post donation. For the two cases where look-back was completed, archive samples were PCR negative and no transmissions were identified. To date, no recipients have been found to be HIV positive after receiving an HIV PCR negative donation from a donor who later seroconverted<sup>1</sup>.

#### **HTLV**

In 2012, HTLV infections identified in the UK, Channel Isles, Isle of Man and the ROI accounted for 4% (10/246) of all infected donors. The majority (80%; 8/10) of these donors were female; this is in contrast to all other infections where male donors predominated. Six HTLV infected donors were non-white (60%; 6/10) and, where known, seven (78%; 7/9) were born outside the UK or ROI. A possible source of infection was identified for 90% (9/10) of donors. Five donors (56%; 5/9) probably acquired their infection through SBMW, and this included three donors who were born in an endemic country and had a heterosexual partner from an endemic country. The source of infection for a further four donors (44%; 4/9) was likely to be an association with an endemic country with no other risk behaviour reported. None of the HTLV infected donors was classified as a seroconverter.

In 2003, the NHSBT/PHE Epidemiology Unit in collaboration with NHSBT and Imperial College established the HTLV National Register for long-term follow up of people affected by HTLV. Recruitment is by clinicians at blood centres and specialist clinics. Participants are asked to complete a baseline self completion questionnaire about their health and HTLV risk factors, flagged in central registries for cancer or death, and followed up about their health and well being every 2-3 years. At the end of 2012, a total of 167 HTLV positive individuals had consented to take part; 85 of these were blood donors. Information from the Register will provide a unique perspective on HTLV since it is the only study of its kind in Europe, and only one of two in the world still recruiting participants.

#### **Treponemal antibodies**

In 2012, donations with treponemal antibodies identified in the UK, Channel Isles, Isle of Man and the ROI, accounted for 32% (79/246) of all infected donors. These were all thought to be due to syphilis infections (past and present), except one where the donor reported a history of yaws. Twenty donors (11 newly tested and nine previously tested donors) had markers of infection and a risk history consistent with having acquired an infection within the last year. This data excludes Scotland because there was insufficient information to determine whether or not infections had been recently acquired. The majority of donors with treponemal antibodies were male (68%; 54/79) and, where known, most were white (74%; 57/77) and born in the UK or ROI (70%; 42/60). Where known, the majority of donors (82%; 42/51) with treponemal antibodies reported SBMW as their probable source of infection.

The probable source of infection for eight donors (16%; 8/51) was sex between men, and five of these donors were non-compliant with DSG. One donor had an infection associated with an endemic country, with no other specific risk reported. Clinicians reported 28 (35%; 28/79) infections among previously tested donors, an increase from 16 (18%; 16/89) in 2011. However, not all of these infections have been acquired since the previous donation, but rather some were past infections that were previously

undetected because of low levels of antibodies close to the test cut-off. The introduction of more sensitive methodologies for serology testing has contributed to an increased detection of historic treponemal infections.

#### Impact of the change to the MSM deferral

It is just over 12 months since the change in the blood DSG for MSM from a permanent to a 12 month deferral in England, Scotland and Wales. It is not possible to report how many extra donors have given blood since this change as the three blood services do not collect this data; men are only asked if they have had sex with another man in the last 12 months. As a proxy measure in an attempt to detect changes among donors, statistical analysis (change point analysis) of the number of new male donors attending city donation sessions pre- and post- the change was carried out. In total 153,228 new male blood donors resident within 25 city centres across England who donated during 2010 and 2011 were extracted from PULSE along with their relevant demographic information. No statistical difference was observed (Sam Lattimore, personal communication) although this data should be treated with caution given the small numbers involved, and the potential lag between a change in DSG and any behavioural change.

As previously described there has been an overall decrease of 18% in the rate of markers of infection per 100,000 donations compared with 2011 data, with a similar downward trend seen across all infections. There continues to be a downwards trend year-on-year. One of the main concerns with any change in the DSG is that the length of the deferral is sufficient to prevent the transmission of a window period infection; this is of particular concern for HBV. As in previous years most HBV infections were chronic infections, only three acute infections were identified. Of the three acute infections one donor did not identify himself as MSM but disclosed sex with a man in the previous 12 months, one donor had a heterosexual risk and one did not disclose any known risk. One HCV positive donor also disclosed a recent MSM risk, however, he also had a history of IDU and this was thought to be a more likely source of the infection, this donor was HIV negative. A total of 15 donors were found to be positive for HIV markers, of these 13 disclosed a possible risk for acquiring their infection. The majority (8) reported SBMW as the most likely risk factor but four were MSM with three reporting sexual contact in the last 12 months; one was compliant with the DSG and had a previously undiagnosed infection. The majority of the donors who were MSM had treponemal antibodies. Of those 51 donors who reported a risk exposure for acquiring syphilis eight were MSM, two of whom were compliant with the DSG and one where it was not possible to ascertain if the donor was compliant. Those donors who were not compliant were asked about their reason for donation and whether they understood the selection criteria. Three donors assessed their risk as low, one did not think that the DSG were important and two did not fully understand the selection criteria.

It is too soon to fully evaluate the impact of the change to the MSM DSG, however, although these data should be treated with caution, to date there is no evidence of an

adverse impact on the number or rate of infections detected on screening. The unit will continue to monitor the impact of the change.

#### 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. Thirty four donors (15%; 34/223) identified in the UK (excluding donors from Scotland), Channel Isles, Isle of Man and the ROI did not disclose information prior to making their donation that would have resulted in them being temporarily or permanently deferred (Table 2.4). Three donors from Scotland who were non-compliant with DSG are not included here because information on their reasons for non-disclosure at the time of donation is not currently provided.

Table 2.4: Infected donors who were non-compliant to donor selection guidelines by reason for non-disclosure in UK (excluding Scotland)<sup>1</sup> and Republic of Ireland, 2012

	Deferral reason									
Reason for non-disclosure	Injecting drug use (IDU)	MSM	Sex between men and women (HR) <sup>2</sup>	Blood transfusion <sup>3</sup>	Tattooing, body/ear piercing, acupunc- ture	Aware of infection	Total			
Didn't think it was important to answer accurately	0	1	1	0	0	2	4			
Comprehension difficulty	2	2	0	0	0	1	5			
Test seeking	0	0	0	0	1	0	1			
Decided personal risk was low or in the past	8	3	0	1	0	0	12			
Embarrassment/ unable to opt out	0	1	1	0	0	0	2			
Other	0	1	0	0	0	1	2			
No information reported	3	2	1	2	0	0	8			
Total	13	10	3	3	1	4	34			

<sup>1.</sup> SNBTS do not provide data to us about reasons for non-disclosure and therefore SNBTS donations are excluded from this table.

The number of donors non-compliant to the DSG varied by infection, as did the type of non-compliance, but most non-compliant donors (53%; 18/34) were infected with HCV. Most of the non-compliances (37%, 13/34), related to IDU and this included 13 of the 18 (72%) HCV infected donors. Six of 10 (60%) non-compliant donors with treponemal antibodies reported sex between men and the other four acquired their infection as a

<sup>2.</sup> Deferrable risks include where the donor has a recent partner who may ever have injected drugs (see the DSG).

<sup>3.</sup> One UK, two abroad.

result of SBMW. Three donors (9%, 3/34) had engaged in sex with a "high risk" partner and three should not have donated blood because they had been given blood transfusions, one in the UK in 1980 and two abroad. A further four donors were aware of their infection status at the time of donation.

For the 34 infected donors who were non-compliant with the DSG in 2012, nearly three quarters (74%; 26/34) gave a reason why they had not complied, a higher number than in 2011 (45%; 13/29). Most (46%; 12/26) understood the relevant question on the DSG, but thought that their personal risk was low. Five donors (19%; 5/26) had difficulty understanding the questions on the DSG and a further four (15%; 4/26) did not think it was important to answer accurately probably due to lack of understanding of the donor selection rationale. The Unit is about to start a survey of blood donors to determine the amount of, and reason for, non-compliance in healthy blood donors who test negative on all the mandated screening tests.

#### 2.4. Additional testing in England and north Wales in 2012

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 2012 by donors with specific histories are shown in Table 2.5.

#### Additional testing for hepatitis B

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, i.e. resolving infections where HBsAg levels have fallen, but before the level of antibodies to HBsAg (anti-HBs) have risen to protective levels. Testing will also detect past exposure to the hepatitis B virus. NHSBT uses a threshold of anti-HBs >100 mIU/ml to retain these donors with sufficient protective immunity.

Table 2.5: Additional testing for anti-HBc, anti-*Trypanosoma cruzi*, anti-malaria and anti-West Nile virus in England and north Wales, 2012

Marker	No. donations tested	% Of all donations tested	No. repeat reactive at screening <sup>1</sup>	% Repeat reactive	No. confirmed positive <sup>2</sup>	% Confirmed positive
Anti-HBc <sup>1,2</sup> Anti- <i>T.</i>	32,606	1.56	106	0.33	40	0.12
cruzi Anti-	2,144	0.10	0	0.00	0	0.00
malaria West Nile	36,541	1.79	1345	3.68	453	1.24
virus NAT	30,000	1.47	0	0.00	0	0.00

<sup>1.</sup> Reactive at screening for anti-HBc and anti-HBs negative or <100 mIU/ml.

<sup>2.</sup> Confirmed anti-HBc positive AND anti-HBs <100 mIU/ml.

Of the 32,606 donations tested in 2012, 40 (0.1%) were confirmed to be anti-HBc positive with anti-HBs levels below 100 mIU/mI (and HBsAg/HBV NAT negative on screening). These donors were removed from the panel and advised that they could no longer donate; five donors selected for anti-HBc additional testing were identified as HBsAg reactive in screening and the additional testing algorithm was not pursued further once this was known. Of the remaining 61 donations reactive to anti-HBc screen testing, the majority (n=47) were deemed to be false reactive, ie were anti-HBc negative in the reference laboratory. The remaining ten donors were confirmed as anti-HBc positive, but had anti-HBs >100 mIU/mI and therefore had sufficient immunity to be returned to the donor panel.

#### Additional testing for Trypanosoma cruzi

Testing for markers of *T. cruzi* by NHSBT is dependent upon the donor reporting a previous transfusion, past residence or rural work in an endemic area. In 2012, there were no donations confirmed positive for *T. cruzi*. Since testing of blood donors began in the UK in 1998, there have only been three confirmed cases; one detected during 1998 and two during 2009<sup>2</sup>.

#### Additional testing for malaria

Testing for markers of malaria by NHSBT is dependent upon the donor reporting travel to, or residence in a malaria endemic area, or history of malaria or tropical fever. In 2012, 453 (1.2%) donations tested for markers of malaria were confirmed antibody positive; this is a statistically significant increase in the proportion confirmed in 2011 (1.2% v 0.6%,  $\chi^2$ =93.63, p<0.001). Six of the antibody positive donations made in 2012 were also malarial DNA positive. These six donors were referred for malaria treatment. Availability of malaria antibody testing has resulted in an extra 36,541 donations from donors who would have otherwise been deferred, and of these, 35,196 would have been released for use, assuming they were also non-reactive to all the mandatory markers of infection. Most of the donors who were retained in the donor pool and whose donations were released for use were repeat donors (68%), 52% were female and, where known, 81% were of white ethnicity.

#### **Additional testing for West Nile virus**

In 2012, West Nile virus (WNV) NAT testing of donations from donors returning from WNV at risk areas between 1 May and 30 November began on 1 May 2012<sup>3</sup>. During 2012, 30,000 donations were screened, none were reactive so all were available for release depending on mandatory screening results.

# 3.0 The risk estimates in the UK, 2010-2012

#### **Key findings**

- the estimated number of potentially infectious window period donations per million donations tested that entered the UK blood supply between 2010 and 2012 was 0.79, 0.035 and 0.16 for HBV, HCV and HIV respectively. These values are almost unchanged from those most recently published for the UK from 2010 to 2011
- at current donation levels of approximately 2.4 million donations each year in the UK, it is estimated that testing will NOT identify approximately two potentially infectious HBV window period donations every year, one potentially infectious HCV window period donation every 12 years and one potentially infectious HIV window period donation every 2.9 years
- donations from new donors that enter the blood supply were estimated to be more likely to be infectious compared with donations from repeat donors
- of the three viruses, HBV was the virus most likely to be missed during 2010-2012 due to a window period donation

#### **3.1 Overview of 2012**

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 is mostly because a blood donation is made during the potentially infectious "window period" (WP) early in the course of infection when the test in use will not detect the marker of infection. In 2012, we calculated window period risk as the risk multiplied by 1 million, which is the number of potentially infectious donations in 1 million donations entering the blood supply, with 95% confidence intervals (by simulation), and the number of donations entering the blood supply before one of those donations can be expected to be a potentially infectious donation.

NOTE: Data is provisional, subject to SACTTI approval in October 2013.

Table 3.1: 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: 2010-2012

Risk due to window period		HBV <sup>1</sup>	HCV <sup>2</sup>	HIV <sup>3</sup>
Number of potentially infectious	All donations⁴	0.79 (0.31-1.49)	0.035 (0.016-0.068	0.14 (0.09-0.30)
window period donations in 1 million	Donations from new donors	2.23 (0.70-5.95)	0.133 (0.043-0.042)	0.18 (0.02-1.77)
donations entering the blood supply (95% CI). This is equal to risk x 1,000,000	Donations from repeat donors	0.65 (0.26-1.18)	0.025 (0.012-0.042)	0.14 (0.09-0.20)
Number of donations	All donations <sup>4</sup>	1.27	29	7.04
(millions) entering the blood supply	Donations from new donors	0.45	7.5	5.44
before 1 of those donations can be expected to be a potentially infectious donation. This is equal to 1/(risk x 1,000,000)	Donations from repeat donors	1.5	39.3	7.24

<sup>1.</sup> HBV testing assumed all donations were tested for markers of HBsAg and HBV DNA using NAT with a window period of 38.3 days. However, Scotland did not commence HBV NAT testing until March 2010.

All NAT testing was on pooled samples of 24 donations.

<sup>2.</sup> Anti-HCV testing and HCV RNA testing with a window period 4 days.

<sup>3.</sup> Combined HIV antigen/antibody testing and HIV NAT with a window period 9 days.

<sup>4.</sup> 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.

## 4.0 Transfusion transmitted infection

#### **Key findings**

- in 2012, there were two confirmed transfusion transmitted infections, one HEV and one parvovirus
- one HBV incident which was reported as pending at the end of 2011 was confirmed as a proven transfusion transmitted infection in 2012

#### **4.1 Overview of 2012**

The NHSBT/PHE Epidemiology Unit receives reports of suspected transfusion transmitted infections (TTIs) from blood centres across the UK. Cases are classified as confirmed according to the definition in Box 1 below.

#### **Box 1: Definition of TTI**

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

The recipient had evidence of infection following transfusion of blood components and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection

#### and, either

At least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection

or

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

Incidents involving HTLV, HCV or HIV infections in recipients who received transfusions prior to the introduction of routine testing are excluded. (Routine testing was introduced in August 2002 for anti-HTLV, September 1991 for anti-HCV & October 1985 for anti-HIV).

During 2012, 46 suspected TTI incidents were reported by blood centres and hospitals throughout the UK (Figure 4.1). Of the 29 cases of suspected bacterial transmission investigated during 2012, 27 were shown not to be TTIs. The remaining two bacterial cases were undetermined, as satisfactory investigation was impossible due to missing or leaking packs (see Box 2 for Serious Hazards of Transfusion [SHOT] recommendations). Of the 17 suspected viral incidents, 13 were concluded not to be TTIs and two investigations (one HEV and one HIV) were pending at the end of 2012. Two reports of suspected viral transmission were confirmed as TTIs, one case of parvovirus transmission and one of HEV transmission. Neither of these infections is currently screened for by the UK blood services. There were no variant Creutzfeldt-Jakob disease (vCJD) investigations in 2012.

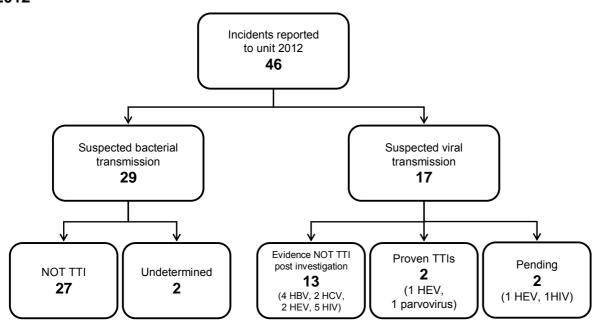


Figure 4.1: Reports of suspected TTIs made to the NHSBT/HPA Epidemiology Unit in 2012

In addition, investigations into 70 reports of suspected bacterial incidents showed no evidence of bacteria in either the pack or the recipient and were therefore reclassified as possible transfusion reactions. Four suspected viral incidents initially reported to the unit were not investigated. This was because positive results were shown to be due to passive transfer (HBV), infection was not confirmed (HCV), infection was present prior to transfusion (HEV) or historic hospital records were not available (HIV).

#### Box 2: Recommendations from SHOT 2012\*

 Retain suspected bacterially contaminated packs, even if near empty, for return to the Blood Service as the residue can be washed out and cultured.

Report a suspected bacterial TTI promptly to the Blood Service to allow recall of any associated packs for testing. If sampling packs locally for bacterial testing, use ports rather than breaching the pack to minimise environmental contamination of the pack.

 Hospitals and centres investigating a possible viral TTI are reminded of the importance of locating any archived recipient samples (transfusion related or not) for testing.

It is important that laboratories facilitate access to those samples (with due consent of appropriate parties including the patient).

One HBV TTI incident, which was reported as pending at the end of 2011, was confirmed as proven and reported to SHOT in 2012. In December 2011 a recipient of multiple transfusions received during surgery in August 2011 was diagnosed with acute HBV, which gradually cleared over the following months. The recipient received components from 16 donors; no evidence of HBV infection was found in 15 of these 16

<sup>\*</sup> Previous recommendations issued by SHOT remain active.

donors. However, one donor showed evidence of exposure to and immunity to HBV on a donation made four months after the implicated index donation. Transmission occurred through fresh frozen plasma (FFP). The implicated donor was asymptomatic, in the very early stages of infection at the time of donation and was unaware of their infection status. The donor had no reported deferrable risks and the only possible reported risk was participation in contact sports. The index donation had been HBsAg screen negative (individual sample testing) and HBV NAT negative (pooled testing). Although testing for HBV DNA is not mandatory, triplex NAT screening is currently used on all donations. Reference laboratory testing of archive samples concluded that the level of HBV DNA was too low to be detected in the pooled NAT screening test. A red cell pack produced from this donation was transfused to an older, immunosuppressed recipient who was not able to clear the infection and developed chronic HBV infection.

One parvovirus incident was confirmed as a TTI in 2012. A child who had been given a red cell transfusion for sickle cell anaemia in September 2012 developed a temperature of 41°C and lymphopenia 48 hours post transfusion. Approximately two weeks after the transfusion, parvovirus B19 DNA, IgG and IgM antibodies were detected in the child. The implicated donation was parvovirus B19 DNA positive, IgG equivocal and IgM antibody negative, but a subsequent sample from the donor was positive in all three tests. The donor and recipient both had parvovirus B19 with the same very common genotype. The child had recovered from infection by the time of the next scheduled transfusion. The 25-year-old repeat donor was asymptomatic, reporting no illness either before or after donation.

One HEV incident was confirmed as a TTI in 2012 and reported to SHOT in 2013. A female recipient underwent stem cell transplant with associated transfusion support in autumn 2011 and developed abnormal liver function tests in May 2012. Stored sample testing showed that the recipient had been HEV RNA negative in December 2011 but was positive in February 2012. The recipient died in autumn 2012 from causes unrelated to HEV infection. The stem cell donor was HEV negative. Thirty-four blood donations were investigated and two donors were confirmed to be HEV RNA positive at the time of donation. Only one donor (Donor A) had a virus with a sequence which matched that of the one found in the recipient. The recipient had received FFP from Donor A. Lookback on the red cell component from Donor A's donation identified a female transfused for a haematological condition. This second recipient was HEV RNA negative, but positive for IgG and IgM antibodies a year after transfusion, which is consistent with a previous HEV infection. Although it was likely that HEV transmission had occurred from Donor A, this could not be confirmed as the lack of HEV RNA positivity in the second recipient precluded HEV typing. Donor A, a 22-year-old repeat male, reported no illness prior to the index donation. The infection had cleared and Donor A had seroconverted when tested six months later. There was an increase in the number of reports of suspected HEV transmissions to investigate in 2012, probably due to increased awareness that HEV can be transmitted by blood. A study is currently

under way to investigate HEV incidence, transmissibility and outcome of transmission in blood donations in England.

Guidance and reporting forms for suspected bacterial, viral or parasitic TTIs for hospitals served by NHSBT can be found on the Requests for Information of Adverse Events and Reactions page at:

http://www.blood.co.uk/hospitals/library/request\_forms/aer/.

For other blood services please contact the local blood supply centre.

Cumulative data and commentary on TTIs may be found in the accompanying "Supplementary Data Tables and Figures" document and in the SHOT Report 2012 which is available on the SHOT website: www.shotuk.org.

## 5.0 Bacterial screening

#### **Key findings**

- the bacterial screening initial reactive rate stabilised during 2012, with an initial reactive rate of 0.43 % and 0.31 % for apheresis and pooled platelets, respectively
- the confirmed positive rate remained low at 0.02% for apheresis platelets and 0.08% for pooled platelets
- skin flora continue 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 has prevented the transfusion of packs containing potentially pathogenic organisms
- an unexpected benefit of bacterial screening has been the identification of bacteraemia and underlying pathology in asymptomatic donors

#### **5.1 Overview of 2012**

All UK blood services currently screen platelets for the presence of bacteria as an additional adjunct to the various risk-reduction measures already in place for the prevention of bacterial transfusion transmitted infections (TTIs). Bacterial TTIs are more frequently associated with platelet packs rather than red cells because platelets are stored at room temperature. This encourages the growth of many bacteria associated with opportunistic infections, including organisms found on the skin or in the oropharynx. As stated in Chapter 4, there were no reported, confirmed bacterial TTIs in 2012, the first full year of reporting. The last confirmed report of a bacterial TTI was in 2009 when two incidents were reported; one incident involving the transmission of *Streptococcus pneumoniae* by apheresis platelets to two recipients and a second incident involving the transmission of *Pseudomonas koreensis* by a red cell transfusion to one recipient. All of the UK blood services use a bacterial culture method, BacT/ALERT, for bacterial screening but with slightly different methods. Only data for NHSBT is presented here.

Bacterial screening was introduced by NHSBT in February 2011; screening was also introduced in the 2000s by Northern Ireland, Scotland and Wales. The initial reactive rate stabilised during 2012 at 0.43% for all apheresis platelets screened and 0.31% of pooled platelets (Table 5.1). Of those initial reactive packs, bacterial growth was cultured from 9.2% of apheresis and 38% of pooled platelets. Further testing by the National Bacteriology Laboratory (NBL) reported 0.02% of apheresis platelet packs tested as confirmed positive and 0.08% of pooled platelet packs; a greater proportion of pooled platelets packs were reported as contaminated than reported in 2011. In addition 0.02% of apheresis and 0.05% of pooled platelets were reported as indeterminate positive in 2012.

Table 5.1: Bacterial screening of platelets by NHSBT using BacT/ALERT. Components tested and results of confirmatory investigations undertaken by NBL, 2012

	Components screened	No. Initial Reactive (%)	No. Confirmed Negative <sup>1</sup> (%)	No. Confirmed Positive <sup>2</sup> (%)	No. Indeterminate Positive <sup>3</sup> (%)	No. Indeterminate Negative <sup>4</sup> (%)
Apheresis platelets Pooled	237,212	1,024 (0.43)	577 (0.24)	36 (0.02)	58 (0.02)	353 (0.15)
platelets	40,863	128 (0.31)	54 (0.13)	30 (0.08)	19 (0.05)	25 (0.06)
Total	278,075	1,152 (0.41)	631 (0.22)	66 (0.02)	77 (0.03)	378 (0.13)

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

#### **Box 5.1. Definitions**

<sup>&</sup>lt;sup>1</sup> Confirmed negative. Index, associated pack or both are negative.

<sup>&</sup>lt;sup>2</sup> **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).

<sup>&</sup>lt;sup>3</sup> **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.

<sup>&</sup>lt;sup>4</sup> **Indeterminate negative.** The bottle is confirmed negative but the index or associated packs are not available to confirm a negative result.

The predominant bacteria cultured from confirmed and indeterminate positive packs were identified as microflora associated with the skin of the donor arm (Table 5.2). 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. The presence of these bacteria in a platelet pack does not represent a failure of donor arm cleansing. These micro-organisms are not thought to result in TTIs. However, other micro-organisms associated with the skin, such as *Staphylococcus aureus*, have the potential to cause significant morbidity if transfused. *S. aureus* contamination may be due to a significant load of these organisms on the skin of the donor, where they commonly reside without causing disease. All donors with evidence of *S. aureus* in their platelet donation are followed up, including asking about any relevant medical history and taking swabs of the venepuncture pre- and post- skin cleansing. Swabs of the nose and throat are also taken. Where appropriate, donors are permanently withdrawn from donation.

Micro-organisms associated with both dental health and disease have been identified during screening. The presence of these bacteria in a platelet pack probably reflects a transient bacteraemia at the time of donation, in some cases due to the donor cleaning their teeth immediately prior to attending to donate. Other micro-organisms usually found in the oropharynx were identified, including *Streptococcus pneumoniae*. Two donations were confirmed positive for the presence of *S. pneumoniae* in 2012; no packs were issued from these donations and both donors were followed up. This finding probably reflects a transient bacteraemia in the donors.

As in 2011 micro-organisms usually found in the gut were isolated from platelet packs and cultured from three apheresis donations and one pooled platelet pack. The presence of these bacteria in a platelet donation could represent undiagnosed disease in the donors. All donors were asymptomatic. *Streptococcus bovis* was isolated from two of these donations and these donors were referred for specialist review.

The 2012 data reflect those seen in 2011 with a more complex microflora, most likely associated with a transient bacteraemia, being seen in component donors who donate platelets by apheresis.

Table 5.2: Likely source of organisms isolated on bacterial screening

	Aph	eresis	Ро	oled
Likely source	Confirmed positive	Indeterminate positive	Confirmed positive	Indeterminate positive
Skin				
Propionibacteria	11	38	18	6
Corynebacteria	0	2 3	0	0
Coagulase	3	3	5	5
negative				
staphylococci				
Staphylococcus	3	8	1	3
saccharolyticus				
Staphylococcus	3	0	2	0
aureus				
Other skin	1	4	0	1
micro-				
organisms				
0				
Oropharynx	_	0	0	4
Oral	5	3	3	1
streptococci	2	0	0	0
Streptococcus	2	U	U	U
<i>pneumoniae</i> Other	5	0	0	3
oropharyngeal	5	U	U	J
micro-				
organisms				
Gut	3	0	1	0
Total	36	58	30	19

## 6.0 PHE Blood Borne Virus Unit

#### **6.1 Overview of 2012**

The Blood Borne Virus Unit (BBVU) is established within the Virus Reference Department at Microbiology Services, PHE Colindale and is jointly funded by PHE and NHSBT. BBVU provides a specialist diagnostic service and undertakes surveillance and research and development activities relating to public health and blood safety. BBVU collaborates with the joint NHSBT/PHE Epidemiology Unit. During 2012, joint projects have included the molecular and epidemiological characterisation of viruses in blood donors and the development of microbiological screening methods in response to new and emerging threats to blood safety.

#### 6.2 Hepatitis B

A study investigating acute and chronic HBV infections in blood donors over a five-year time-frame was recently completed<sup>4</sup>. A total of 355 HBV-infected donors, 11 (3%) of whom had markers indicating recent infection, were identified between July 2005 and June 2010. Retrospective epidemiologic and serologic data were collated and laboratory testing was carried out to determine the HBV genotype, viral load, and prevalence of clinically significant mutations and to detect hepatitis delta virus (HDV) coinfection.

Molecular characterisation studies in the chronic infections demonstrated five HBV genotypes (A-E), of which D (45%), A (20%), and E (20%) were the most prevalent. A strong association was seen between genotype and the ethnicity of the donor (p<0.001) and between genotype and place of residence (p=0.006). Furthermore, clinically significant mutations were observed across the hepatitis B surface antigen (17%), basal core promoter (25%) and precore (78%) regions. An antiviral resistance profile was identified in one donor. Evidence of HDV coinfection was found in 2% of donors.

The blood donors with acute HBV infection presented a very different demographic and virological profile from donors with a chronic HBV infection identified over the same time period. The findings confirm the belief that while chronic HBV infections are in the most part a feature of population migration, acute HBV infections were likely to have been acquired within the UK and, in our series, from other infected UK-born persons.

Collectively, these data show that the integration of virologic and demographic data allows us to more accurately construct a profile of HBV-infected blood donors. The study demonstrated the diversity of HBV in asymptomatic chronic infections detected in blood donors in England and north Wales and demonstrates 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 highlights the importance of using screening assays capable of detecting a broad range of genotypes and mutations. In

addition, phylogenetic analysis of acute HBV-infected donors can potentially lead to identification of undeclared risk factors that donor health questionnaires may fail to identify.

#### 6.3 Hepatitis E

The recent recognition of the wider public health implications of hepatitis E has emphasised the need to understand the impact of parenteral transmission of the virus. Descriptions of chronic HEV infection in the immunocompromised host have elevated hepatitis E from a self-limiting acute infection to one where persistent viraemia may lead to raised transaminases and histological features of chronic hepatitis. As a high proportion of UK blood components are given as haematological support to immunocompromised patients, the issue of HEV and blood safety warrants further investigation. A joint study conducted by NHSBT and PHE began in October 2012 and is addressing the growing concern about HEV and blood safety. The study aims to define i) the incidence of HEV in donors ii) the extent of HEV transmission from virus containing components and iii) the outcome of acquiring HEV from transfused components.

The study remains ongoing but initial findings indicate a high HEV incidence in donors with an associated high transmission rate to recipients. Analysis of possible factors associated with transmission showed red cells were less likely to be linked to transmission than platelets or FFP. Analyses of measurable immune response and virological factors demonstrated antibody titres to be lower and HEV RNA viral loads to be higher in donations that resulted in transmission. Understanding the outcome of receiving HEV-containing components remains an essential part of this study. Initial observations indicate a more prolonged viraemia in immunocompromised recipients, but so far chronic infection has not been observed. It is anticipated that determining outcomes will be a rather complex task, with variables such as the underlying medical condition of the recipient and the interventions required to manage it playing a significant role. The study is due for completion at the end of 2013.

#### 6.4 Hepatitis C

Approximately 77 HCV infected blood donors are identified by NHSBT each year. Currently no information is available regarding the genotype distribution and trend in genotype profile of HCV in this population. This project aimed to provide genotype distribution and identify trends in phylogenetic profile of HCV infections in NHSBT blood donors from July 2005 to June 2010 and to compare the results of this study with data collected through the Sentinel Surveillance system at the Health Protection Agency. Three hundred and thirteen HCV positive blood donor samples were analysed, 75% of these were HCV RNA positive. Genotypes 1a (39%) and 3a (31%) were found to be the most prevalent HCV genotypes in the blood donor population.

#### **6.5 HTLV**

Infection with HTLV is occasionally detected within the blood donor population, usually confined to individuals from endemic countries or female sexual partners of men from these areas. In 2002, NHSBT introduced testing for the presence of HTLV antibodies on all blood donations in England and Wales. However, routine screening and subsequent confirmatory testing of "reactive" donors is primarily serologically based with a high proportion of indeterminate Western Blot results. These unresolved profiles may represent true HTLV I or II infection, false positive results, or seroconverters, making not only confirmatory diagnosis problematic but posing delays in patient monitoring and aftercare. To address some of these issues an in-house assay for the detection of HTLV I and HTLV II has been developed and implemented into confirmatory testing by NTMRL. Additional molecular characterisation methods have also been established and sequencing studies undertaken on ten samples from HTLV I infected blood donors; data indicate that they all cluster within the transcontinental subgroup A of the Cosmopolitan subtype.

## 7.0 Tissue and cord blood donors

#### **Key findings**

- tissue and cord blood donor surveillance has been developed to include a scheme to
  monitor infections in cornea donors. In 2012, 11 cornea donors tested by NHSBT
  were confirmed to have markers of infection. This included one donor positive for
  markers of HIV who was known to have given multiple tissues; this donor is also
  included among the deceased category in this report
- testing by NHSBT identified five surgical bone donors with markers of infection in 2012. This included one donor with markers of HTLV; the first since HTLV testing was introduced in 2002
- two cord blood donors were confirmed by NHSBT to be positive for treponemal antibodies, suggestive of past infection, and 40 donors with malarial antibodies
- thirty cord blood donors tested positive for antibody to hepatitis B core antigen and with levels of antibody to hepatitis B surface antigen <100 mIU/ml. The corresponding figures for cornea, deceased and living surgical bone donors were 21, two and ten respectively
- consistent with previous years, the number of tissue and cord blood donors positive for markers of infection in 2012 was low, but because of the very low numbers of donors the rates exceed those estimated among donations from blood donors

#### 7.1. Overview of tissue and cord blood donors in 2012

Currently, routine surveillance is in place to collect data on the number and markers of infection in deceased, surgical and cord blood donors tested by the UK blood services. In 2012 for the first time, the same data for cornea donors tested by NHSBT were included in this scheme. NHSBT currently tests donors for donations processed via two of the four UK eye banks (Manchester and Bristol). Donations from Scotland and north Wales, which are currently managed by the Manchester Eye Bank, are included. Corneas are donated by deceased donors, some of whom have also donated other tissues and will therefore have a duplicate report in the surveillance scheme. This year, such donors are included in both the cornea and deceased categories but in future years we intend to identify these multi-tissue donors, allowing the reporting of a total rate of infection for all deceased tissue donors (including cornea donors) with samples tested by NHSBT. In 2012, 11 cornea donors were shown to be positive for markers of infection, most commonly treponemal antibodies. One cornea donor was positive for markers of HIV and known to have given multiple tissues; this donor is also included among the deceased category in this report.

Five surgical bone donors were shown to have markers of infection in 2012, excluding positivity for antibody to hepatitis B core antigen (anti-HBc) only (Table 7.1). This included one surgical bone donor positive for markers of HTLV and four positive for treponemal antibodies. Although HTLV has been identified in deceased and cord blood

donors in previous years, this is the first HTLV infection identified in surgical bone donors tested by NHSBT since testing was introduced in 2002.

Among cord blood donors tested by NHSBT in 2012, two were confirmed positive for markers of treponema suggestive of long-past infection. These two positive treponema tests among cord blood donors are unlikely to reflect an antenatal screening 'miss' but rather the sensitivity of tests used by NHSBT.

Overall, the number of tissue and cord blood donors positive for markers of infection in 2012 was low and similar to that previously reported. Each year there are very low numbers of tissue and cord blood donors, and the estimated rates of detection of markers generally exceed those among donations from blood donors. Rates are particularly high for treponemal antibodies among cornea donors and surgical bone donors. Cornea donors who have not donated organs and surgical bone donors have the oldest average age of all donors and markers of treponema probably reflect a syphilis infection acquired a long time in the past.

For all donors shown to be positive for markers of infection by NHSBT, information about their probable source of infection is sought. For deceased donors, donor selection relies upon obtaining information from family or close contacts and this information is not routinely available to the surveillance scheme. Although possible risk information should be more readily available for surgical bone donors, in 2012 almost three-quarters of all infected donors had no identified probable source of infection despite follow-up.

Screening of tissue donations in England and north Wales for anti-HBc commenced in December 2006 and, unlike blood donations, testing is mandatory for tissue and cell donations. Donations that are anti-HBc positive and have levels of anti-HBs below 100 mIU/ml may reflect either past resolved HBV infection or infection in the second window phase and are discarded. During 2012, 21 such donations were identified from cornea donors, two from deceased donors and ten from surgical bone donors. Follow-up information is not available for donors who are anti-HBc positive with anti-HBs levels below 100 mIU/ml and so it is not known how they may have been exposed to HBV.

No infections were identified among tissue and cord blood donors in Scotland and Northern Ireland in 2012.

#### 7.2. Tissue donors in 2012 and 2001-2012

During 2012, samples from 2,924 cornea donors, 560 deceased donors and 3,543 surgical bone donors were tested by NHSBT (Table 7.1). Excluding screening for anti-HBc, which is usually indicative of past HBV infection, markers of infection were identified in 11 cornea donors; eight had treponemal antibodies and three had markers of HBV, HTLV or HIV respectively. The cornea donor positive for markers of HIV was known to have given multiple tissues; this donor is also included among the deceased

category in this report. Five surgical bone donors had markers of infection, four with treponemal antibodies, generally the most common marker in these donors and probably reflecting a long-past syphilis infection, and one was anti-HTLV positive.

Table 7.1: The number and rate of tissue donors positive for markers of HBV, HCV, HIV, HTLV and/or treponemal antibodies and anti-HBc, as tested by NHSBT, 2012 and 2001-2012<sup>1</sup>

Reporting	porting Donor					Numbe	r positive		
period	type	number tested	HBV <sup>2</sup>	HCV	HIV	HTLV	Treponemal antibodies	Total <sup>3</sup>	Anti- HBc <sup>4</sup>
	Corneas	2,924	1	0	1	1	8	11	21
2012	Rate <sup>5</sup>		34.2	0.0	34.2	34.2	273.6	376.2	718.2
	Deceased	560	0	0	1	0	0	1	2
	Rate <sup>5</sup>		0.0	0.0	178.6	0.0	0.0	178.6	357.1
	Surgical bone	3,543	0	0	0	1	4	5	10
	Rate <sup>5</sup>		0.0	0.0	0	28.2	112.9	141.1	282.2
2001-	Deceased <sup>6</sup>	5,103	1	4	2	1	8	16	10
2012	Rate <sup>5</sup>		19.6	78.4	39.2	19.6	156.8	313.5	196.0
	Surgical bone <sup>7</sup>	42,630	13	12	1	1	56	83	44
	Rate <sup>5</sup>		30.5	28.1	2.3	2.3	131.4	194.7	103.2

- 1. Mandatory anti-HBc testing commenced in December 2006; data presented here are for the period 2007-2012 only.
- 2. Excludes positivity for anti-HBc only, ie HBsAg and/or HBV nucleic acid testing (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.
- 6. One dual infection (HCV/treponemal antibodies) ie a total of 15 infected donors.
- 7. Three dual infections (two HCV/treponemal antibodies, 1 HBV/treponemal antibodies) ie a total of 80 infected donors.

The estimated rate of treponemal antibodies among cornea and surgical bone donors was 273.6 and 112.9 per 100,000 donors; approximately nine and four times the rate among donations from new blood donors.

Since the start of tissue donor surveillance in 2001, 16 deceased donors and 83 surgical bone donors with markers of infection have been identified (excluding donors who tested positive for anti-HBc only). This is equivalent to rates of 313.5 and 194.7 positive tests per 100,000 donors tested, respectively (Table 7.1). Additional information on the rates of infection among deceased, living surgical bone and cord blood donors

between 2001 and 2012 can be found in the "Supplementary Data Tables and Figures" document. Excluding positivity for anti-HBc only, treponemal antibodies were the most commonly detected marker in tissue donors. As in blood donors, these can indicate current or past syphilis infection as well as cross reactivity with other treponema which cause infection rarely seen in the UK, ie yaws and pinta. HIV infection is extremely rare among tissue donors; to date, only two HIV infections have been detected in deceased tissue donors and one surgical bone donor. Since surveillance began, only two HTLV infections have been detected in tissue donors, one in 2011 in a deceased donor and one in 2012 in a living surgical bone donor.

#### 7.3. Cord blood donors in 2012 and 2001-2012

A total of 2,449 cord blood donors were tested by NHSBT during 2012 (Table 7.2). NHSBT cord blood collection is targeted at an ethnically diverse population in the London area to ensure a diverse supply of donations and this may, in part, explain the high frequency of markers of exposure to HBV (see below).

Table 7.2: The number and rate of cord blood donors positive for markers of HBV, HCV, HIV, HTLV or treponemal antibodies and anti-HBc, as tested by NHSBT, 2012 and 2001-2012<sup>1</sup>

Reporting	Donor	Total				Numb	er positive		
period	type	number tested	HBV <sup>2</sup>	нсч	HIV	HTLV	Treponemal antibodies	Total <sup>3</sup>	Anti- HBc <sup>4</sup>
2012	Cord blood Rate <sup>5</sup>	2,449	0 0.0	0 <i>0.0</i>	0 0.0	0 0.0	2 81.7	2 81.7	30 1225.0
2001- 2012	Cord blood Rate <sup>5</sup>	17,815	0 <i>0.0</i>	12 67.4	0 0.0	8 <i>44.</i> 9	8 <i>44</i> .9	28 157.2	126 707.3

- 1. Mandatory anti-HBc testing commenced in December 2006; data presented here are for the period 2007-2012 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.

Two donors were confirmed positive for treponemal antibodies, probably reflecting long-past syphilis infection. There were no confirmed infections for HBV, HCV, HIV or HTLV in 2012.

Thirty cord blood donors were confirmed anti-HBc positive with levels of anti-HBs <100 mlU/ml. The frequency of donors testing positive for anti-HBc with levels of anti-HBs

<100 mIU/ml in 2012 was considerably higher than that of the other mandatory markers and accounted for 91% (30/33) 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.</p>

Of the 928 cord blood donors receiving an additional test for malaria in 2012 (Table 7.3), 40 tested positive for malaria antibodies (a rate of detection of 4,310.3 per 100,000 donors tested). This higher rate, reflecting exposure to malaria among cord blood donors, is probably due to the ethnic diversity of this donor population. One of the malaria antibody positive donors was also PCR positive, indicating a current infection. None of the 96 cord blood donors tested positive for *T. cruzi* markers during 2012.

Table 7.3: The number and rate of cord blood donors positive for markers of malaria and *Trypanosoma cruzi*, as tested by NHSBT, 2012 and 2001-2012

Reporting period	Ма	laria	Trypanosoma cruzi				
Reporting period	No. tested	No. positive	No. tested	No. positive			
2012	928	40	96	0			
Rate <sup>1</sup>		4,310.3		0.0			
2001-2012	3,778	133	333	0.0			
Rate <sup>1</sup>		3,520.4		0.0			

#### 1. Rate per 100,000 donors.

Cumulatively, 28 cord blood donors with markers of infection (excluding positivity for anti-HBc only) have been identified since the start of this surveillance programme, approximating to a rate of 157.2 infections per 100,000 donors tested (Table 7.2). In contrast to deceased and surgical bone donors, where treponemal markers were most frequently detected (Table 7.1), HCV markers were the most common markers detected in cord blood donors (12 donors) over this time period. No markers of HIV infection were found in cord blood donors. Although only two HTLV infections were detected in tissue donors during 2001-2012, HTLV infections accounted for almost a third of infections in cord blood donors (29%, 8/28); excluding positivity for anti-HBc only. Cord blood donors positive for HTLV infection and their GPs are contacted regarding the test results and the risks of breast feeding explained. All HTLV positive donors are referred to a specialist clinic for follow-up.

During the period 2007-2012, 126 cord blood donors tested positive for anti-HBc with levels of anti-HBs <100 mIU/mI, a rate of 707.3 per 100,000 donors (Table 7.2). During

2001-2012, 333 cord blood donors tested by NHSBT had malaria markers, a rate of 3,520.4 per 100,000 donors (Table 7.3). Markers of *T. cruzi* have never been detected in cord blood donations tested by NHSBT.

# 7.4. Tissue and cord blood donors from Scotland (2005-2012) and Northern Ireland (2007-2012)

Surveillance of infections in tissue and cord blood donors tested by the Scottish National Blood Transfusion Service (SNBTS) started in 2005. Tissue and cord blood donors are not split by donor type but most are surgical bone donors. To the end of 2012, 12 donors with markers of infection were identified in total, nine of which were treponemal antibody positive, giving an overall rate of infection of 80.6 per 100,000 donors (Table 7.4).

Table 7.4: 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 (2007-2012)

Testing	Total			Num	ber positiv	/e	
centre and donor type	number tested	HBV <sup>1</sup>	HCV	HIV	HTLV	Treponemal antibodies	All markers
SNBTS							
Donors <sup>2</sup>	14,894	3	0	0	0	9	12
Rate <sup>3</sup>		20.1	0.0	0.0	0.0	60.4	80.6
NIBTS							
Surgical Bone							
Samples <sup>4</sup>	1,452	0	1	0	0	1	2
Donors	871	0	1	0	0	1	2
Rate <sup>3</sup>		0.0	114.8	0.0	0.0	114.8	229.6
NIBTS							
Cord Blood							
Samples <sup>4</sup>	1,803	0	0	0	0	0	0
Donors	1082	0	0	0	0	0	0
Rate <sup>3</sup>		0.0	0.0	0.0	0.0	0.0	0.0

<sup>1.</sup> Excludes positivity for anti-HBc only, i.e. HBsAg and/or HBV NAT positive only. Includes one HBsAg negative/HBV DNA positive tissue donor from Scotland (2011).

<sup>2.</sup> Donors are mainly surgical bone donors but samples from deceased, amnion and stem cell donors may be included.

<sup>3.</sup> Rate per 100,000 donors.

<sup>4.</sup> 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 the Northern Ireland Blood Transfusion Service (NIBTS) started in 2007. Cumulatively, markers of infection have been detected in two surgical bone donors (one HCV and one treponemal antibody positive), a rate of 229.6 per 100,000 donors. No markers of infection have been detected in cord blood donors.

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

The differences in the demographic and epidemiological characteristics of tissue, cord blood and blood donor populations are reflected both in the differences in the infections detected and risk exposures of infected donors. Donor Selection Guidelines (DSG; www.transfusionguidelines.org.uk), are similar for blood, tissue and cell donors, except for MSM donor selection criteria in England and Scotland, and donations in all cases are made on a voluntary basis. However, there are differences in the ways in which donors are recruited. Blood donors are self-selecting in that they bring themselves forward for donation at donation clinics. Tissue and cord blood donors differ because they are approached in hospitals by members of clinical staff or a donation team and asked whether they would like to donate. All consenting donors, whether blood, tissue or cord blood donors, complete a donor health check questionnaire. For deceased donors, the questionnaire must be completed by a family member or the next of kin, i.e. the information is not obtained first hand as for all other donors. Risk exposures or ethnicity are therefore rarely obtained for deceased donors, and family members and close contacts are only followed up if they are thought to be at risk of infection. Cord blood donors will have usually been screened antenatally for HIV, HBV and treponemal antibodies and would be deferred from donation if infection was detected in those tests.

Table 7.5 shows the age, ethnicity and risk exposures for infected deceased, surgical bone and cord blood donors between 2001 and 2012. Risk information is not available for most tissue donors found positive for markers of infection. For surgical bone donors, in 57/82 cases (70%) no risk exposure was identified either because of incomplete follow-up (45%; 37/82) or because no risk was identified despite a post-test discussion (24%; 20/82). Where a risk exposure was available, seven (28%; 7/25) surgical bone donors reported SBMW as their most likely risk. A further six surgical bone donors (24%; 6/25) reported "other" blood contact as the possible source of their infection (including tattoo/acupuncture/body piercing, nosocomial exposure and/or possible occupational exposure) while six (24%; 6/25) reported blood transfusion as their most likely risk (all six transfusions occurred prior to 1980). Other possible risk exposures reported by infected surgical bone donors are shown in Table 7.5. Where known, the majority (95%, 55/58) of infected surgical bone donors were of white ethnicity. No risk exposures were identified for any of the 13 deceased tissue donors, for the reasons given above.

Table 7.5: Age, ethnicity and risk exposures reported by infected tissue donors, as tested by NHSBT, 2001-2012<sup>1</sup>

Charactaristics (maternal	Dece	eased	Surgio	cal bone	Cord
Characteristics (maternal characteristics for cord blood donors)	Male	Female	Male	Female	blood
Number	11	4	36	44	28
Mean age (years)	57	63	69	69	33
Ethnic background					
White	0	0	24	31	13
Black African	0	0	0	0	4
Black Caribbean	0	0	1	0	5
Chinese	0	0	0	1	0
Indian/ Pakistani/ Bangladeshi	0	0	1	0	3
Not available	11	4	10	12	3
Risk exposures reported					
Injecting drug use (IDU)	0	0	0	1	1
Sex between men and women (SBMW)	0	0	2	5	3
Blood transfusion recipient	0	0	0	6	2
Other blood contact <sup>2</sup>	0	0	5	1	3
Mother to infant	0	0	0	2	1
Born in an endemic country	0	0	2	1	2
Interviewed – no risk identified	$NA^3$	$NA^3$	8	12	3
Incomplete follow-up	NA <sup>3</sup>	NA <sup>3</sup>	19	16	13

<sup>1.</sup> Excludes donors with positivity for anti-HBc only, i.e. HBsAg and/or HBV NAT positive only.

The rate of infection (both past and present) is generally higher in tissue and cord donors as compared to blood donors. This reflects the demographic differences between the tissue, cord 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, with a greater number of male donors as compared to female (77% male). Surgical bone donors have the oldest average age of all donor groups shown here (69 years), with donations usually made by patients undergoing hip-replacement surgery.

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

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

Safe Supplies: Completing the Picture

Slightly more females are tested as compared to males (55% female). Cord blood donors represent the youngest donor group overall with an average age of 33 years.

# 8.0 Deceased solid organ donor surveillance

#### 8.1 Key findings

- in 2012, 3,945 organs were donated, of which 3,377 organs were transplanted from 1,078 deceased solid organ donors. This included 1,045 organs from 433 donors after circulatory death and 2,332 organs from 645 donors after brain death
- in 2012, 1,164 deceased solid organ donors were tested across the UK including 660 donors following brain-stem death and 504 following circulatory death
- in 2012, the distribution of initially reactive screening test results for blood-borne viruses was as follows: HBV core total antibodies, 30; HBV surface antigen, 2: HCV antibodies, 5. No reactivity for HIV antigen/antibodies was seen. HTLV data was not routinely available from all centres during 2012

#### **8.2 Overview of 2012**

For the first time in 2013, complete data for all proceeding deceased solid organ donors during the previous calendar year have been available for infection surveillance purposes. Currently, deceased organ donors are routinely tested for the following infectious agents: HIV, HBV, HCV, HTLV, Cytomegalovirus (CMV), Epstein-Barr virus (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. In addition, HTLV serology was not consistently performed across all centres during 2012.

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. While comprehensive data encompassing all potential donors who were tested for markers of infection is desirable and most informative, it was not possible to capture all these data for 2012.

In 2012, 1,164 deceased solid organ donors were tested across the UK (Table 8.1), of whom 723 (62.1%) were positive for at least one of the microbiological markers routinely tested at screening. 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. The newly generated infection surveillance data is presented by calendar year and for 2012, it includes proceeding deceased solid organ donors only. In future years, the organ surveillance system will be extended to include markers of infection among non-proceeding organ donors, of which there were 609 in 2012; this will better reflect the prevalence of relevant infection

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

As expected, the positivity rate varied considerably by infectious marker. In line with the known epidemiology of Herpesviruses, the most frequently occurring reactive marker was for EBV which was detected among approximately four in five (85.6%) donors for whom a test result was available; this was followed by CMV, which was detected in approximately half (51.6%) of donors.

Deceased solid organ donors are categorised as those occurring either following brain death (DBD) or circulatory death (DCD). In 2012, 56.7% (660) of deceased donors were classified as DBD, and 43.3% (504) as DCD.

Males accounted for 53.4% of all solid organ donors, including 60.3% of DCDs and 48.0% of DBDs (Table 8.2). While the median age of all donors was 53.0 years (IQR 41.0-64.0), males were younger than females among both DBDs (median age of 50.0 compared to 53.0 years) and DCDs (median age of 56.0 compared to 57.0). The ethnicity of organ donors was broadly similar to that seen among blood donors, with the majority (91.1%) being of white ethnicity, with a similar proportion of donors among DBDs and DCDs.

Individuals may donate multiple organs; as a result, 3,377 organs were transplanted from 1,078 deceased solid organ donors. This included 1,045 organs from 433 DCDs, and 2,332 organs from 645 DBDs.

#### Individuals with positive microbiology

Two (0.2%) individuals were reactive for HBV surface antigen (HBsAg). Both were male and aged between 25 and 45, one of whom was of black or black British ethnicity, and the other of white ethnicity. Four organs were donated by these individuals in total, and all four were transplanted.

HBV core total antibody (anti-HBc) was detected in 29 (2.6%) individuals, 28 of whom were HBsAg negative, indicating past exposure to HBV. Excluding one of the males described above who was also HBsAg positive, indicating HBV infection at the time of death, there were 12 females and 16 males with median ages of 51.5 (IQR 40.3 - 58.3) and 54.0 (IQR 49.0 - 58.0), respectively.

Table 8.1: The number and proportion of markers of infection identified among deceased solid organ donors during 2012

	HBs	sAg	Anti-	НВс	НС	CV	Н	IV	CN	ΛV	EB	V <sup>1</sup>	H1	ΓLV	To	KO <sup>1</sup>	Sy	ph <sup>1</sup>
l l	n	%*	n	<b>%</b> *	n	<b>%</b> *	n	<b>%</b> *	n	%*	n	%*	n	<b>%</b> *	n	<b>%</b> *	n	%*
Proceeding solid organ																		
donors																		
Negative	1162	99.8	1122	96.4	1159	99.6	1164	100.0	556	48.4	37	14.5	1115	99.9	584	82.7	878	99.3
Reactive	2	0.2	29	2.5	5	0.4	0	-	593	51.6	219	85.5	1	0.1	122	17.3	6	0.7
Unavailable at offering	0	-	13	1.1	0	-	0	-	15	-	908	-	48	-	458	-	280	-
Total	1164	-	1164	-	1164	-	1164	-	1164	-	1164	-	1164	-	1164	-	1164	-
Donors after brain death																		
Negative	659	99.8	639	97.3	656	99.4	660	100.0	326	49.6	25	16.7	640	99.8	347	86.8	495	99.2
Reactive	1	0.2	18	2.7	4	0.6	0	-	331	50.4	125	83.3	1	0.2	53	13.3	4	8.0
Unavailable at offering	0	-	3	-	0	-	0	-	3	-	510	-	19	-	260	-	101	-
Total	660	-	660	-	660	-	660	-	660	-	660	-	660	-	660	-	660	-
Donors after circulatory																		
death																		
Negative	503	99.8	483	97.8	503	99.8	504	100.0	230	46.7	12	11.3	475	100.0	237	77.5	383	99.5
Reactive	1	0.2	11	2.2	1	0.2	0	-	262	53.3	94	88.7	0	-	69	22.5	2	0.5
Unavailable at offering	0	-	10	-	0	-	0	-	12	-	398	-	29		198		119	-
Total	504	-	504	-	504	-	504	-	504	-	504	-	504	-	504	-	504	-
Solid organ donors from																		
whom organs were																		
transplanted																		
Negative	1076	99.8	1040	97.6	1074	99.6	1078	100.0	524	49.2	34	14.2	1034	99.9	542	83.1	812	99.4
Reactive	2	0.2	26	2.4	4	0.4	0	-	541	50.8	205	85.8	1	0.1	110	16.9	5	0.6
Unavailable at offering	0	-	12		0	-	0	-	13	-	839	-	43		426	-	261	-
Total	1078		1078	-	1078		1078	-	1078	-	1078	-	1078	-	1078	-	1078	-

<sup>1.</sup> Results for EBV, Toxoplasma and syphilis serology are not required at the time of organ offer and are therefore often missing from the database, but would have been available post donation.

Table 8.2: Demographic characteristics of deceased solid organ donors following brain and circulatory death

	Decease don	ed organ ors		s after death	Donors after circulatory death		
	n	%	n	%	n	%	
Sex							
Male	621	53.35	317	48.03	304	60.32	
Female	543	46.65	343	51.97	200	39.68	
Age Group							
0-16	31	2.66	23	3.48	8	1.59	
17-24	84	7.22	52	7.88	32	6.35	
25-34	79	6.79	46	6.97	33	6.55	
35-44	154	13.23	100	15.15	54	10.71	
45-54	264	22.68	161	24.39	103	20.44	
55-64	274	23.54	159	24.09	115	22.82	
65-74	221	18.99	96	14.55	125	24.80	
75-84	57	4.90	23	3.48	34	6.75	
Ethnicity							
White	1,081	92.87	605	91.67	476	94.44	
Asian or Asian/British	23	1.98	12	1.82	11	2.18	
Black or Black-British	18	1.55	15	2.27	3	0.60	
Chinese/Oriental	4	0.34	3	0.45	1	0.20	
Other/Mixed	13	1.12	7	1.06	6	1.19	
Unknown/not reported	25	2.15	18	2.73	7	1.39	
Total	1,164		660		504		

HCV IgG was detected in five donors, including three males and two females. Both males were of white ethnicity and aged 22 and 26, each donated one organ, both of which were transplanted. One female donor of black or black British ethnicity was aged 21, two were white and aged 38 and 41 at the time of death. In total seven organs were donated, of which five were transplanted.

HTLV IgG was detected in one donor, who was female, white and aged over 60 at the time of death. Three organs were donated, of which two were transplanted.

Treponemal antibodies were detected in six individuals, including three males and three females. Males were aged between 51 and 54, two of whom were of white ethnicity and one of unknown ethnic group. Females were aged between 48 and 58, two of whom were of white ethnicity and one of Asian or Asian British ethnicity. In total, 18 organs were donated of which 12 (66.7%) were transplanted.

*Toxoplasma gondii* IgG was detected in 122 individuals including 66 males and 56 females. The median age of males and female was similar at 58 (IQR 50 - 64.75 years) and 59, respectively (IQR 49.8 - 68.0 years). The majority of both male and female organ donors were of white ethnicity, comprising 90.9% (60/66) and 94.6 (53/56),

respectively. In total, 363 organs were donated, of which 306 (84.3%) were transplanted.

EBV IgG result was available at time of organ offer for 256 (22.0%) donors, and was detected in 219 individuals including 113 males and 106 females. The median age of males and females was similar at 55 (range 42.0 – 66.0 years) and 53 (range 43.0 – 59.8 years), respectively. As with other markers of infection, the majority of donors were of white ethnicity, comprising 93.8 % (106/113) and 95.2% (101/106) of male and female donors, respectively. In total, 737 organs were donated, of which 639 (86.7%) were transplanted.

Where test results were available, approximately half (593; 51.0%) of all individuals were seropositive for CMV, including 300 males and 293 females, with median ages of 57.0 (IQR 45.0-66.0) and 57.0 (IQR 47.0-66.0), respectively. Those who were CMV IgG positive were significantly older than those with negative serology (mean age of 57.0 and 47.4, respectively). The majority of both male and female donors were of white ethnicity, comprising 91.0% (273/300) and 88.7% (260/293), respectively. In total 1,885 organs were donated, of which 1,597 (84.7%) were transplanted.

# 9.0 Surveillance of emerging infections

#### 9.1 Overview of 2012

#### Introduction

The NHSBT/PHE Epidemiology Unit produces an emerging infection report: a monthly listing of items about emerging infection pertinent to transfusion, from a wide variety of publicly available published sources (see our web page<sup>5</sup> 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. The main purpose of the emerging reports is to alert the blood and tissue services – via the Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) and the Joint UKBTS/PHE Professional Advisory Committee (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. This is one of several reports on emerging threats that these committees receive and the arrangements for monitoring emerging infection threats to the UK blood supply are outlined in a position statement (see the JPAC position statement on emerging infection<sup>6</sup>).

Situations being closely monitored in 2012 included:

#### **West Nile virus**

The unit continued to monitor reports of WNV outbreaks, particularly from Europe. During 2012 JPAC added further areas to the geographical disease risk index (GDRI) for application of the WNV selection guidelines including Algeria, Croatia, Greece, Hungary, Kosovo and Serbia<sup>7</sup>. The WNV deferral was replaced with testing in 2012 to avoid deferring increasingly large numbers of donors. Donors returning from WNV affected areas between 1 May and 30 November without symptoms suggestive of, or a diagnosis of, WNV infection can now be accepted with a validated negative NAT result rather than deferring the donor for four weeks (see Chapter 2 for data on numbers tested). However vigilance is maintained for any threat from other infections that may be potentially imported by donors returning from WNV affected areas that are no longer covered by the four week deferral period, for example, babesiosis from the US<sup>8</sup>.

#### Malaria

Locally acquired *Plasmodium vivax* cases were reported in Greece for the second year in a row. As in 2011, the cases mainly involved migrant workers and local residents living and working in an agricultural area and thus presented a low risk to tourists and potential UK donors. This situation continues to be monitored.

#### Middle East respiratory syndrome coronavirus

Reports of cases of severe respiratory illness acquired in Middle Eastern countries associated with a novel coronavirus (later named Middle East respiratory syndrome coronavirus [MERS-CoV]) were first noted in September<sup>9</sup>. Cases of MERS-CoV continue to be reported with severe respiratory symptoms and 50% case fatality (as of May 2013). There is evidence of limited human to human transmission and although the risk to either travellers to the Middle East acquiring infection or of UK residents contracting the infection in the UK remains low at the time of writing, the evolving situation is being closely monitored for signs of any potential for significant impact on the UK blood supply.

#### Crimean-Congo haemorrhagic fever

CCHF remains a concern with the first known case of imported CCHF to the UK<sup>10</sup>. CCHF is endemic in many countries in Africa, Asia, the Middle East and Eastern Europe and is an emerging disease in the Balkans<sup>11</sup>. Many domestic and wild animals are hosts for the tick-borne virus which causes CCHF. Transmission to humans can occur through contact with the ticks or infected animal blood/tissues. CCHF can also be transmitted from one person to another through contact with infected blood or other body fluids.

#### **Dengue**

The first locally acquired cases of Dengue in the Madeira Islands, a popular UK tourist destination, were reported in September 2012<sup>12</sup>. The outbreak had waned by mid December although sporadic cases were reported after this. Over 2,000 cases were reported with 23 reported cases imported to the UK<sup>13</sup>. No action on donor deferrals was taken at this time but any change to the situation will be reviewed as necessary.

#### **Rabies**

From October it was reported that rabies was re-emerging in Greece in wild and domestic animals. The risk to UK travellers was thought to be low as Western Macedonia, where the first animal cases were reported, is not a major tourist destination, however this is being monitored. The UK is classified as a rabies-free country with no rabies being found in terrestrial animals. An imported human case of rabies was reported in the UK in 2012, rabies had been contracted in India<sup>14</sup>. Rabies is known to be transmissible by organs<sup>15</sup> although no cases of transfusion transmitted rabies have been reported.

#### Xenotropic murine leukaemia virus related virus update

Further Xenotropic murine leukaemia virus related virus studies by the original groups who found links with the virus to disease states were published in 2012 finding no association with chronic fatigue syndrome or ME and no association with prostate cancer<sup>16, 17, 18</sup>.

## 10.0 Glossary of abbreviations

**Anti-** antibody to

Anti-HBc antibody to hepatitis B core antigen antibody to hepatitis B surface antigen

BBVU Blood Borne Virus Unit

**CCHF** Crimean-Congo haemorrhagic fever

**CMV** Cytomegalovirus

**CNS** Coagulase Negative Staphylococci

**DBD** donor after brain death

DCD donor after circulatory death donor selection guidelines

**EBV** Epstein-Barr virus **FFP** fresh frozen plasma **HBV** hepatitis B virus

**HBsAg** hepatitis B surface antigen

HCV hepatitis C virusHDV hepatitis delta virusHEV hepatitis E virus

HIV human immunodeficiency virus
HTLV human T-cell lymphotropic virus
IBTS Irish Blood Transfusion Service

IgGimmunoglobulin GIgMimmunoglobulin MIDUinjecting drug user

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 database

**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
SHOT Serious Hazards of Transfusion

**SNBTS** Scottish National Blood Transfusion Service

TTI Transfusion Transmitted Infection

**UKBTS** United Kingdom Blood Transfusion Service

vCJD variant Creutzfeldt-Jakob Disease

WNV West Nile virus WP window period

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