

## Transfusion-Transmitted Bacterial Infections – Haemovigilance Data of German Blood Establishments (1997–2010)

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### Keywords

TTBI · Frequency · Severity · Pre-donation sampling ·  
Limitation of platelet shelf life ·  
Blood components · Pathogenicity · Haemovigilance

### Summary

**Methods:** In order to evaluate the benefit of risk minimisation measures, reporting rates of transfusion-transmitted bacterial infections (TTBI) were calculated on the basis of annual reports and distributed blood components. Following the implementation of risk minimisation measures in 2003 and 2008, a comparison of pre- and post-implementation periods was performed. **Results:** During a period of 14 years, 90 cases of TTBI were confirmed, 34 were caused by red blood cell (RBC) concentrates, 5 by fresh frozen plasma, and 51 by platelet concentrates (PCs). The overall reporting frequency was 1 TTBI in 1.91 million RBC units; 1 TTBI in 0.094 million PC units, and 1 TTBI-associated fatality in 0.57 million PC units. From 2001–2004 the reporting rate was 13.7 per million PC units; 2005–2008, after the implementation of pre-donation sampling; it was 10.8 per million PC units ( $p > 0.5$ ). After limitation of the shelf life (2008), the reporting rate decreased to 4.49 per million PC units ( $p = 0.12$ ), and one case of related fatality was reported. Agents with low pathogenicity were reported in 14 of 41 immunosuppressed patients (34%) but only in 1 of 13 patients with non-haematological/oncological diseases. **Conclusion:** TTBI and associated fatalities could be gradually reduced by the risk minimisation measures, but further strategies such as implementation of sensitive screening tests or pathogen-reducing approaches should be discussed.

### Schlüsselwörter

TTBI · Häufigkeit · Schweregrad · «Pre-donation sampling» ·  
Begrenzung der Thrombozytenhaltbarkeit ·  
Blutkomponenten · Pathogenität · Hämovigilanz

### Zusammenfassung

**Methode:** Zur Bewertung des Nutzens von Risiko minimierenden Maßnahmen wurde die Meldefrequenz von transfusionsbedingten bakteriellen Infektionen (TTBI) auf der Basis der jährlichen Meldungen und der Anzahl der ausgelieferten Blutkomponenten errechnet. Es erfolgte dann ein Vergleich der Zeiträume vor und nach der Implementierung von Risiko minimierenden Maßnahmen in den Jahren 2003 und 2008. **Ergebnisse:** In dem Zeitraum von 14 Jahren wurden 90 TTBI-Fälle bestätigt, 34 wurden durch Erythrozytenkonzentrate (EK) verursacht, 5 durch gefrorenes Frischplasma und 51 durch Thrombozytenkonzentrate (TK). Die Gesamtmelderate war eine TTBI auf 1,91 Millionen EK-Einheiten; eine TTBI auf 0,094 Millionen TK-Einheiten und ein transfusionsassoziierter Todesfall auf 0,57 Millionen TK-Einheiten. Die Melderate für den Zeitraum 2001–2004 lag bei 13,7 pro Million TK-Einheiten und nach der Implementierung des «Pre-donation sampling» bei 10,8 pro Million TK-Einheiten ( $p > 0,5$ ). Nach der Begrenzung der Haltbarkeit (2008) reduzierte sich die Melderate auf 4,49 pro Million TK-Einheiten ( $p = 0,12$ ). Seitdem wurde ein transfusionsbedingter Todesfall gemeldet. Erreger mit niedriger Humanpathogenität wurden bei 14 von 41 immunsupprimierten Patienten nachgewiesen, aber nur bei einem Patienten ohne hämatologische/onkologische Erkrankung. **Schlussfolgerung:** Die Melderate von TTBI sowie assoziierter Todesfälle konnte durch Risiko minimierende Maßnahmen schrittweise gesenkt werden; dennoch sollen weitere Pathogen reduzierende Strategien wie z.B. der Einsatz sensitiver Suchtests oder Pathogen inaktivierender Verfahren diskutiert werden.

## Introduction

Transfusion-transmitted bacterial infection (TTBI) was described 2005 by a standardised case definition [1]. Various haemovigilance systems emphasised the significance of this serious transfusion reaction during the last decade [2–7]. Before 2004, septic reactions to platelet transfusion were estimated to occur approximately in 1 of 25,000 transfusions [8, 9]. Published contamination rates varies between 1:5,000 and 1:20,000 [10, 11]. Meanwhile different risk reduction measures have been recommended and implemented [12–14].

In order to evaluate the effectiveness of our policy, we compared reporting rates of TTBI involving components and fatalities from 1997 to 2010 – before and after the implementation of risk-reducing measures.

## Material and Methods

Reports of TTBI from 1997 to 2010 were collected and evaluated since the implementation of the German Transfusion Act (Transfusionsgesetz; TFG). Treating physicians should send initial reports of TTBI to the blood establishments or directly to the Paul-Ehrlich-Institute. Physicians are requested to add any missing data such as main symptoms, clinical course, identification, and categorisation of the pathogenic agent affecting the recipient as well as data of involved blood components. The confirmed TTBI back-up plasma samples or blood components from the transfused product were analysed microbiologically.

Pathogenic agent testing of the recipient blood was mostly performed in the medical institute for microbiology associated with the hospital where the recipient was treated, whereas the pathogenic agents of the donor blood were tested in the medical institute for microbiology associated with the blood establishment. In the case of university hospitals, the donor and recipient testing was performed in the same institute for microbiology. Samples were analysed by aerobic and anaerobic cultures, and bacterial identification was performed according to the general standards. A TTBI was defined by clinical criteria associated with a culture-positive residual component or a culture-positive recipient demonstrating the same bacteria as determined by, for example, antibiotic sensitivity.

In 2002 and 2008, the German Advisory Committee Blood (Arbeitskreis Blut; AK Blut) recommended two risk minimisation measures. The implementation by the blood donation establishments occurred on a voluntary basis. In order to achieve a reduction in microbial contamination of blood components, pre-donation sampling for platelet concentrates (PCs) has been recommended since June 2003 (AK Blut, opinion 27). This includes the separation and removal of at least 15 ml after venipuncture before drawing donors' blood.

Since June 2008, a limitation of the shelf life of PCs has been recommended (AK Blut, opinion 38). In order to reduce the danger of fatal transfusion reactions caused by bacterial contamination, the storage of PCs should be limited to 4 days (4 × 24 h), beginning at midnight of the day the blood was collected.

### Statistical Analysis

The reporting rate of TTBI was calculated on the basis of confirmed TTBI and the number of transfused blood components. The figures of transfused fresh frozen plasma (FFP), PCs and red blood cell (RBC) concentrates must be reported to the PEI annually according to Section 21 of the TFG.

The difference between the reporting frequencies of TTBI was calculated using the odds ratio (with 95% confidence limits) and the exact chi-

**Table 1.** Reported and confirmed TTBI and associated fatalities related to blood components (1997–2010)

	1997	1998	1999	2000	2001	2002	2003 <sup>a</sup>	2004	2005	2006	2007	2008	2009	2010	1997–2010
Reported TTBI	5	18	10	10	15	17	11	8	25	16	18	20	16	36	225
TTBI after administration of															
RBC concentrates	4	5	1	0	4	1	2	2	3	2	6	3	0	1	34
Pooled PCs	0	3	3	1	1	3	3	1	4	3	1	2 <sup>b</sup>	1	0	26
Apheresis PCs	0	0	1	3	3	3	2	2	3	3	1	1 <sup>b</sup>	1	2	25
FFP	0	4	0	0	0	0	0	0	1	0	0	0	0	0	5
Total	4	12	5	4	8	7	7	5	11	8	8	6	2	3	90
TTBI-related fatalities after administration of															
RBC concentrates	2	2	0	0	0	0	0	0	0	0	0	0	0	0	4
Pooled PCs	0	1	0	0	0	0	1	0	1	0	0	0 <sup>b</sup>	1	0	4
Apheresis PCs	0	0	0	1	0	1	0	1	0	1	0	0 <sup>b</sup>	0	0	4
Total	2	3	0	1	0	1	1	1	1	1	0	0	1	0	12

<sup>a</sup>Implementation of the pre-donation sampling (AK Blut: opinion 27, 2002).

<sup>b</sup>Limitation of the shelf life of PCs to 4 days (AK Blut: opinion 38, 2008).

**Table 2.** Reporting frequency of TTBI related to blood components (1997–2010)

	1997–2000		2001–2004		2005–2008		2009–2010		1997–2010	
	units issued × 10 <sup>6</sup>	TTBIs (total no.) per 10 <sup>6</sup>	units issued × 10 <sup>6</sup>	TTBIs (total no.) per 10 <sup>6</sup>	units issued × 10 <sup>6</sup>	TTBIs (total no.) per 10 <sup>6</sup>	units issued × 10 <sup>6</sup>	TTBIs (total no.) per 10 <sup>6</sup>	units issued × 10 <sup>6</sup>	TTBIs (total no.) per 10 <sup>6</sup>
Reporting frequency of TTBI for the period										
RBC concentrates	16.62	(10) 0.63	17.05	(9) 0.55	18.01	(14) 0.80	9.36	(1) 0.11	61.04	(34) 0.56
PCs	1.29	(11) 8.50	1.38	(18) 13.73	1.75	(18) 10.77	0.94	(4) 4.49	5.36	(51) 9.51
FFP	5.72	(4) 0.63	4.92	(0) 0.00	4.65	(1) 0.22	2.26	(0) 0.00	17.55	(5) 0.28

**Table 3.** Blood components (given in million units) issued by German Blood Services between 1999 and 2009. Notifications of distribution and consumption according to the German Transfusion Act (TFG Section 21)

Year	RBC units × 10 <sup>6</sup>		PC units × 10 <sup>6</sup>		Pooled PC units × 10 <sup>6</sup>	Apheresis PC units × 10 <sup>6</sup>	FFP units × 10 <sup>6</sup>	
	distribution	consumption*	distribution	consumption*	distribution	distribution	distribution	consumption*
2000	4.17	3.93	0.35	0.33	0.14	0.19	1.50	1.43
2001	4.25	4.03	0.34	0.32	0.12	0.21	1.43	1.38
2002	4.26	4.12	0.34	0.33	0.18	0.20	1.26	1.23
2003	4.11	3.93	0.33	0.30	0.11	0.21	1.08	1.05
2004	4.43	4.26	0.37	0.36	0.14	0.23	1.15	1.11
2005	4.44	4.29	0.40	0.38	0.15	0.24	1.07	1.03
2006	4.43	4.29	0.43	0.41	0.17	0.25	1.09	1.05
2007	4.50	4.35	0.45	0.43	0.17	0.27	1.27	1.22
2008	4.64	4.49	0.47	0.45	0.18	0.28	1.22	1.17
2009	4.68	4.54	0.47	0.44	0.17	0.28	1.13	1.10
Sum	43.91	42.23	3.95	3.75	1.53	2.36	12.2	11.77

\*Estimated.

square test (p values below 0.05 were considered as significant). Therefore the periods before and after the implementation of risk minimisation measures were compared; these are the periods before (2001–2004) and after implementation of pre-donation sampling (2003) as well as the periods before (2005–2008), and after the limitation of the PC shelf life (2008).

## Results

Between 1997 and 2010, a total of 225 suspected cases of TTBI were reported, and 90 cases could be confirmed based on the available laboratory data (table 1). 34 of these infections were caused by the RBC concentrates, 51 by PCs and 5 by FFP. Five of the 12 confirmed fatalities occurred between 1997 and 1998, and 4 of these cases were caused by RBC concentrates. Eight fatalities occurred after the administration of PCs (4 pooled PCs and 4 apheresis PCs); 6 of 8 PCs had reached the end of their shelf life (4th or 5th day after manufacture). The last case with fatal outcome after the administration of PCs occurred in 2009.

During the observational period of 14 years, reporting frequencies of TTBI varied between 0.8 and 0.1 cases per million

transfused RBC concentrates and between 0.6 and 0.0 cases per million transfused FFP units (table 2). The reporting frequency for PCs was 13.7 cases per million units during the period from 2001 to 2004 and 10.8 cases during the period from 2005 to 2008 after the implementation of pre-donation sampling. A comparison of these two periods did not demonstrate a statistical significance (odds ratio 0.78, 95% confidence limits 0.41–1.51; p value: 0.5042). After the limitation of the shelf life for PCs in 2008, the reporting frequency decreased to 4.5 cases per million units during the period from 2009 and 2010 but a comparison with the period from 2005–2008 did not demonstrate a statistical significance either (odds ratio 0.42, 95% confidence limits 0.14–1.23; p value: 0.1198).

During a period of 10 years (2000–2009), 3.95 million PCs were distributed by the German Blood Services, 1.53 million units of pooled PCs and 2.36 million units of apheresis PCs (table 3). During this period, 42 TTBI were reported after the administration of PCs, including 7 cases with fatal outcome. 20 TTBI were caused by pooled PCs and 22 cases by apheresis PCs. This is in line with an overall reporting frequency of 1 TTBI in 0.094 million PC units and 1 TTBI with fatal outcome in 0.57 million PC units. For pooled PCs, the

**Table 4.** Results of microbiological analyses in 90 cases of transfusion-transmitted bacterial infections (1997 to 2010)

Agent (genus/species)	Number of blood components with recipient related microbiological analysis				Clinical course of recipients		Fatalities caused by	
	RBCs	PCs	FFP	sum	not fatal	fatal	RBCs	PCs
Agents with low pathogenicity								
<i>Staphylococcus capitis, epidermidis, hominis, saprophyticus and spp.</i>	9	18	2	29	28	1	0	1
<i>Micrococcus luteus</i>	1	0	0	1	1	0	0	0
<i>Corynebacterium spp.</i>	1	1	0	2	2	0	0	0
<i>Propionibacterium acnes</i>	3	2	0	5	5	0	0	0
Total number	14	21	2	37	36	1	0	1
Agents with medium/high pathogenicity								
<i>Pseudomonas aeruginosa</i>	0	0	1	1	1	0	0	0
<i>Staphylococcus aureus</i>	5	6	1	12	10	2	1	1
<i>Streptococcus pyogenes, agalactiae</i>	0	6	0	6	3	3	0	3
<i>Bacillus cereus</i>	0	8	0	8	8	0	0	0
<i>Escherichia coli</i>	1	1	0	2	2	0	0	0
<i>Enterobacter erogenes, amnigenus</i>	1	1	0	2	2	0	0	0
<i>Klebsiella oxytoca, pneumoniae</i>	3	4	1	8	6	2	0	2
<i>Pantoea agglomerans</i>	2	1	0	3	3	0	0	0
<i>Serratia marcescens</i>	2	1	0	3	2	1	1	0
<i>Yersinia enterocolitica</i>	4	0	0	4	2	2	2	0
<i>Enterococcus cloacae, spp.</i>	1	1	0	2	1	1	0	1
<i>Acinetobacter iwoffii</i>	0	1	0	1	1	0	0	0
<i>Stenotrophomonas maltophilia</i>	1	0	0	1	1	0	0	0
Total number	20	30	3	53	42	11	4	7
Total number of all agents	34	51	5	90	78	12	4	8*

\*In 6 of 8 cases PC were administered at day 4 or day 5 after manufacture.

reporting frequency is 1 case in 0.077 million PC units and for apheresis PCs 1 case in 0.107 per million PC units. During the same period, 43.91 million RBC concentrates were issued. 23 cases of RBC-associated TTBI and no case of RBC-associated fatalities were confirmed. This complies with a reporting frequency of 1 TTBI in 1.91 million RBC units.

24 pathogenic species of 9 genera of bacteria were detected during microbiological analyses (table 4). In 37 of the 90 cases, pathogenic agents with low pathogenicity could be identified, such as *Staphylococcus epidermidis* and *Propionibacterium acnes*, and in 53 cases agents with medium to high pathogenicity were found, such as *Klebsiella pneumoniae*, *Serratia marcescens* etc.

The most frequently identified pathogenic agents were *S. epidermidis* (29 cases), and *Staphylococcus aureus* (12 cases), which is part of the skin or airway flora. In most cases with fatal outcome (10 of 11 cases), agents with high pathogenicity were found, such as *Yersinia enterocolitica*, *K. pneumoniae*, *S. marcescens*, and *Streptococcus pyogenes* (table 4).

Underlying diseases of the recipients were reported in 54 of 90 confirmed TTBI cases. TTBI occurred in 41 immunosuppressed (haematological/oncological) patients (76%) and in

13 patients (24%) with non-haematological/oncological diseases such as bleeding episodes because of trauma or duodenal ulcer surgical interventions. Pathogenic agents with low pathogenicity were found in 14 of 41 immunosuppressed patients (34%) and in 1 of 13 patients with non-haematological/oncological diseases. Accordingly, pathogenic agents with medium to high pathogenicity were detected in 27 of 41 immunosuppressed patients (66%) and in 12 of 13 non-immunosuppressed patients.

### Case Reports

#### Case 1

Two apheresis PCs were manufactured from one donation. The apheresis PCs were irradiated 1 day after manufacture. Platelets were transfused to two oncological patients with non-Hodgkin's lymphoma or acute myeloid leukaemia on the 4th day after manufacture. Both patients developed high fever with shock symptoms during transfusion or immediately after the end of the transfusion; they had to be treated in an intensive care unit. One patient died, the other patient recovered from a severe sepsis. *K. pneumoniae* was found in the blood culture of both patients. The pathogenic agent could be identified by PCR testing, and agreement between strains isolated from recipients and residual components was confirmed.

A bacterial culture test (BacT/ALERT (bioMérieux, Nürtingen, Germany) and Pall assay (Pall GmbH, Dreieich, Germany)) was performed from the pre-donation sampling bag and did show a positive result 3 days after transfusion and 7 days after manufacture.

#### Case 2

A 69-year-old female patient with polycythaemia vera and blast crisis received two RBC concentrates and two pooled PCs. She developed chills, fever, tachycardia and haematuria. Blood testing revealed a rise in LDH, a decrease in haptoglobin, and an increasing coagulation disorder (disseminated intravascular coagulopathy). The patient was transferred to the intensive care unit and died within few hours because of progressive sepsis and circulatory failure. Within 8 h, bacterial culture showed a positive result, and *Streptococcus agalactiae* was detected in the blood samples of the recipient and the residual buffy coat. The pooled PC was transfused 4 days after manufacture.

## Discussion

According to former studies, the reporting rates of TTBI range from 1:10,000 to 1:100,000 platelet units [14]. The SHOT report 2009 confirmed a total of 22 TTBI during the last 10 years, representing a reporting frequency of 1 case in 117,000 PC units [2]. Despite the implementation of bacterial screening testing, the American Red Cross published TTBI frequencies between 1:40,000 and 1:193,000 depending on the collecting procedure. The fatality rate was 1 in 500,000 PC units [8, 14].

This data compares well with the German haemovigilance data. We found an overall reporting frequency of 1 TTBI in 94,000 PC units and 1 fatal outcome in 570,000 units. The frequency was higher in pooled PCs than in apheresis PCs without confirming a significant difference.

As shown in various studies, testing of PCs by aerobic and anaerobic cultures (BacT/ALERT) did not differ significantly between apheresis PCs and pooled PCs [10–12]. Bacterial contamination was found in 0.02–0.09% (1:5,000 to 1:1,100) of apheresis PCs and 0.05–0.06% (1:2,500 to 1:1,500) of pooled PCs (confirmed positive bacterial cultures).

The different frequencies of culture-positive and reported TTBI are due to a number of factors. Awareness and attention of the treating physician is needed to interpret clinical signs of sepsis, such as fever, changes in blood pressure and rigors, as a transfusion-associated event. Bacterial levels in blood components as well as the pathogenicity of the transfused species play an important role for the manifestation of septic reactions. Finally concomitant treatment such as antibiotic treatment and underlying diseases of the recipient are important factors for the severity of a TTBI.

The interaction between transfused bacterial agents and the underlying disease of the recipient is supported by our data.

Pathogenic agents with low pathogenicity were almost only found in immunosuppressed patients, whereas agents with medium to high pathogenicity were detected also in non-immunosuppressed patients. It could be assumed that not all bacterially contaminated PC units unavoidably lead to a septic reaction. The severity of bacterial infections also seems to be influenced by the bacterial level at the time when blood components are transfused. In our reported cases with fatal outcome, 6 of 8 PCs were at the end of the shelf life when transfused, indicating a high bacterial level due to long incubation times.

In order to interpret the benefit of the recommended risk-reducing measures, this multifactorial aetiology must be considered. Removal of the initial 10–40 ml of blood after venipuncture before drawing donors' blood has been shown to reduce the bacterial load introduced into manufactured blood components by 40–90% [15]. The clinical significance of the pre-donation sampling was demonstrated by data from a haemovigilance program that showed a concomitant reduction in septic transfusion reactions, which were associated with skin organisms, after implementation of a 40 ml diversion pouch for whole blood-derived platelets [16]. It could be assumed that this measure is effective in reducing bacterial infections caused by blood components contaminated with skin bacteria at the time of phlebotomy, whereas infections caused by symptomatic donors with bacteraemia will not be prevented. However, the limitation of the PC shelf life focus on the prevention of severe bacterial infections due to a high bacterial level after a longer incubation time but will not be suitable to avoid infections with skin bacteria in immunosuppressed patients.

For further reduction of TTBI, new strategies will be discussed. More effective and reliable screening tests could provide more precise and timely results, and pathogen reduction technology might be an effective approach in the future. Scientific evaluations are needed to characterise advantages and disadvantages and to balance the benefits, risks, and costs of these strategies.

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## Disclosure Statement

The authors declare that they have no conflicts of interest relevant to the manuscript submitted to TRANSFUSION MEDICINE AND HEMOTHERAPY.

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