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Compliance of blood donors in Germany with non-sexual deferral criteria

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Abstract

Background and Objectives: In addition to mandatory testing of blood donations, the deferral of donors in the case of various sexual and non-sexual risk exposures ensures the safety of blood products in Germany. The study aimed to quantify non-disclosure of non-sexual risk exposures, as no data are available so far.

Materials and Methods: We conducted an anonymous online survey among whole-blood donors with successful donations between January and March 2020. Data on travel to countries with endemic malaria, recent mild or febrile infections, tattoos or piercings and drug use were collected. We analysed non-compliance in relation to donor demographics by multivariable analyses.

Results: Altogether, 5.4% of the donors were non-compliant. Non-disclosure was highest for mild infection with 3.3% of donors, followed by febrile infections (1.4%), travel to malaria endemic countries (0.7%) and body modifications (0.5%). Intravenous drug use was negligible in our study population. Age was a predictor for all investigated risks, with higher prevalence in younger age groups. Prevalence ratios for non-disclosure of body modifications and mild infection were higher in females than males. Donation in blood establishments with mobile services was associated with higher non-disclosure of mild infections.

Conclusion: The considerable degree of non-compliance in some donor groups reflects the prevalence of risk factors in the underlying population (e.g., body modification) as well as probable tendency to socially desirable responding. Donor education should not focus exclusively on sexual risk behaviour, as undisclosed non-sexual exposures may bear risks for recipients and donors.

Keywords

blood donors, compliance, deferral, non-sexual risk exposures

Highlights

- In addition to compliance with selection criteria for sexual risk exposures, full disclosure of non-sexual risks is crucial for patient and donor safety. This is the first nationwide study in Germany that investigated compliance with donor deferral criteria.
- In our study, 1 in 20 donors did not disclose relevant travel to malaria endemic areas, mild or febrile infections, tattoos/piercings or drug use. Younger age was the strongest predictor of non-compliance for all risk exposures.

- Donations at mobile services might be more prone to non-compliance with donor selection criteria, probably because of fewer available donation appointments that donors do not want to miss.

INTRODUCTION

In order to prevent transfusion-transmissible infections (TTIs), testing of all blood donations for human immunodeficiency virus (HIV), hepatitis B, C, E virus (HBV, HCV, HEV) and syphilis is mandatory in Germany. Moreover, donors are deferred from donation in case of exposures associated with infection risks including risky sexual behaviour, recent travel to certain countries and invasive medical treatment, in order to prevent infections in the window phase or those not tested. Candidate donors can refer to the website of the respective blood service or the Federal Centre for Health Education to check for general eligibility criteria prior to donation. In Germany, donors can donate whole blood after qualifying at their first visit. Donors' risk exposures are determined using a donor health questionnaire and assessed by physicians, and all donors are informed in writing that they should report any illness that occurred shortly after donating to the blood service.

For maximum prevention of TTIs, a complete disclosure of potential risk exposures is essential, especially in case of untested pathogens. Therefore, compliance with deferral criteria is an important indicator for ensuring the safety of blood products. Most studies have focused on donors' compliance with deferral criteria for sexual risk behaviour, as sexually transmitted infections pose a threat to blood safety. However, the relevance of other risk factors for TTIs was shown in donor populations [1, 2]. So far, no data exist for the extent of non-disclosure of non-sexual-risk exposures among whole-blood donors in Germany. We have therefore included questions about recent travel, body modifications, intravenous drug use (IVDU) and mild and febrile infections in a compliance study, which primarily focused on sexual risks [3]. Data analysis aimed to identify donor populations that may need intensified donor education.

MATERIALS AND METHODS

We conducted an anonymous online survey among whole-blood donors in Germany, as has already been described in detail [3]. Briefly, 21 blood establishments (BEs), which represent approximately 80% of the German donor population, invited all non-deferred donors within an 8-week period between January and March 2020 by handing over an invitation flyer immediately after donation. The donors were asked to complete an anonymous online questionnaire including questions about drug use, recent travel, tattoo/piercings and (febrile) infections as well as socio-demographic characteristics.

According to the national hemotherapy guidelines, infection risks were defined as follows:

1. Persons with febrile illness or diarrhoea within 4 weeks prior to donation (hereafter: febrile illness).
2. Persons with a mild infection (e.g., respiratory) within 1 week prior to donation (mild infection).
3. Persons who travelled to a malaria endemic region 6 months prior to donation (malaria risk).
4. Persons with a new tattoo or piercing (ear, other) within 4 months prior to donation (body modification).
5. Persons who have ever injected drugs (IVDU).

Prevalence of non-compliance with selection criteria for infectious risk exposures is given with 95% confidence interval (95% CI). Prevalence estimates were post-stratified for sex and age group considering the cluster sampling in BE using data on invited blood donors as well as the total donor population in Germany in the study period (first quarter 2020) to check the representativeness of study results. Association of non-compliance with socio-demographic data was assessed using modified Poisson regression with robust error estimation providing prevalence ratios (PRs) in a univariate analysis [4].

Donor characteristics that are possibly relevant for the identification of donors with increased need for information about risk exposures were obtained from multivariable analyses of associations between non-disclosure of risks and socio-demographic items. For this purpose, modified Poisson regression models with stepwise backward elimination of variables with a p-level threshold of 0.05 were used. Only data that were known at the time of donation (age, sex, donor status, type of donation service, residence) were considered.

The Ethics Committee of the Berlin Chamber of Physicians decided that ethics approval was not required because the survey study was performed completely anonymously (Ref. Eth-oA 15/19). All participants had to provide informed consent through the survey website before starting the survey. The questionnaire could be cancelled at any time and the consent could be withdrawn.

RESULTS

BEs invited 290,834 donors whose demographic characteristics corresponded to the total donor population in Germany in the study period (Table 1). Altogether, 14,882 complete questionnaires could be analysed. Most of the study participants were repeat donors ($n = 14{,}426$; 97%) and male ($n = 9327$; 63%). Proportions of participating male and repeat donors were higher than for invited donors. Age distribution of participants was comparable to invited donors, with a median age of 46 years (interquartile range 31–55 years).

Altogether, 802 (5.4%) donors had not indicated their recent mild or febrile infection, recent invasive body modification, travel to malaria endemic region or IVDU in the donor health assessment.

Non-disclosure of infection risks was highest for mild infection with 3.3% of donors (Table 2). The non-disclosure of mild infections was strongly age-dependent with a clearly higher prevalence in the younger age groups, and was significantly higher in women than men (χ^2-test $p < 0.001$) (Table 3).

A similar pattern of non-disclosure—although with lower prevalence—was also observed for febrile illness (1.4%) as well as for body modification (0.5%). Travel-associated risk of malaria infection was not indicated at the time of donation by 0.7% of all donors without significant age or sex associations.

Young women under 35 years of age were found to have remarkably higher non-compliance than other donor populations for non-sexual risks. Besides the significant prevalence differences to older women for all risk exposures, we found a significantly higher prevalence compared to men in this age group for mild infections (5.2% vs. 3.9%, χ^2-test, $p < 0.05$) and body modifications (1.8% vs. 0.4%, χ^2-test, $p < 0.001$). The highest overall prevalence of non-compliance was found in women under 25 years for mild infections (5.4%, 95% CI: 4.2%–6.9%), febrile illness (3.4%, 95% CI: 2.4%–4.6%) and body modifications (2.0%, 95% CI: 1.3%–3.0%), and in women aged 25–34 years for malaria risk (1.2%, 95% CI: 0.7%–2.1%).

Non-disclosed IVDU was negligible in our study population, with only five donors reporting past IVDU, including one with IVDU within the last 12 months.

Overall, non-disclosure of any of the investigated non-sexual risk exposures was significantly higher in women (6.9%, 95% CI: 6.2%–7.6%) than in men (4.5%, 95% CI: 4.1%–5.0%).

Non-compliance was generally higher in new donors than in repeat donors, reflecting the age differences of the donor groups: 75% of the new donors were younger than 35 years, but only 30% of the repeat donors were.

Post-stratified non-compliance prevalences that consider possible age and gender biases in the study population as well as BE cluster sampling (Table 2) showed no differences from the study results. It can therefore be assumed that the study population represents the total whole-blood donors in Germany well, despite the somewhat lower proportions of participating new donors and women.

Variable selection for identification of socio-demographic factors that are associated with non-compliance showed that age was a predictor for all investigated risks (Table 4). Younger age groups carried a higher non-compliance risk for non-sexual exposures. Furthermore, sex dependence was found for non-disclosure of body modifications and mild infection, with higher PR for female donors. An additional association was found between the kind of blood service and non-disclosure of mild infections, with higher PR for blood donation at Red Cross Services.

TABLE 1 Demographic characteristics of participants, invited donors and the total donor population in Germany in the study period.

	Participants	Invited donors[a], $n = 290{,}834$ (%)	Total donor population, $n = 937{,}887$ (%)
Donor status			
FTD	455 (3.1%)	10.0	12.1
RD	14,426 (96.9%)	90.0	87.9
Sex			
Female	5555 (37.3%)	42.4	43.2
Male	9327 (62.7%)	57.6	56.8
Age			
18–24 y	1994 (13.4%)	15.4	15.9
25–34 y	2660 (17.8%)	17.0	18.2
35–44 y	2344 (15.8%)	14.2	14.6
45–54 y	3709 (24.9%)	23.2	22.8
55+ y[b]	4175 (28.1%)	30.2	28.5

Abbreviations: FTD, first-time donor; RD, repeat donor, y, years.
[a]Data provided by 19 BEs.
[b]Age groups 55–64 y and 65+ y were merged due to available strata for the total donor population.

DISCUSSION

Deferral of candidate donors with higher risk for TTIs reduces the transmission of pathogens that are either missed by mandatory

TABLE 2 Prevalence of non-compliance with non-sexual risk exposures—Numbers and proportions of participating donors and post-stratified proportions considering BE-specific FTD proportion and age and sex distribution of invited donors as well as of the total donor population in Germany in the study period.

	Study population			Post-stratified invited population		Post-stratified total population	
	n	%	95% CI	%	95% CI	%	95% CI
Malaria risk	100/14,858	0.7	0.6–0.8	0.6	0.4–1.0	0.7	0.4–1.1
Body modification	70/14,868	0.5	0.4–0.6	0.5	0.3–0.7	0.6	0.4–0.8
Mild infection	477/14,510	3.3	3.0–3.6	3.3	2.9–3.7	3.3	2.9–3.8
Febrile illness	203/14,694	1.4	1.2–1.6	1.4	1.2–1.8	1.5	1.2–1.8
IVDU[a]	5/14,853	0.03	0.01–0.08				

Abbreviations: BE, blood establishment; CI, confidence interval; FTD, first-time donor; IVDU, intravenous drug use.
[a]Post-stratified prevalence was not calculated due to zero prevalence in most BEs.

TABLE 3 Numbers and proportion of non-compliance in certain donors and univariate analysis of association between donor demographics and non-compliance.

	Malaria risk					Body modification				Mild infection					Febrile infection				
	n	%	95% CI	PR	95% CI	*n*	%	95% CI	PR	95% CI	*n*	%	95% CI	PR	95% CI	*n*	%	95% CI	PR	95% CI
Donor status																				
FTD	7/455	1.5	0.7–3.2	2.4	1.1–5.1	8/454	1.8	0.9–3.5	4.1	2.0–8.5	25/448	5.6	3.8–8.1	1.7	1.2–2.6	13/443	2.9	1.7–5.0	2.2	1.3–3.8
RD	93/14,402	0.6	0.5–0.8	Ref.		62/14,413	0.4	0.3–0.6	Ref.		452/14,061	3.2	2.9–3.5	Ref.		190/14,250	1.3	1.2–1.5	Ref.	
Sex																				
Female	37/5546	0.7	0.5–0.9	1.0	0.7–1.5	54/5549	1.0	0.7–1.3	5.7	3.2–9.9	217/5408	4.0	3.5–4.6	1.4	1.2–1.7	97/5484	1.8	1.5–2.2	1.5	1.2–2.0
Male	63/9249	0.7	0.5–0.9	Ref.		16/9319	0.2	0.1–0.2	Ref.		260/9102	2.9	2.5–3.2	Ref.		106/9210	1.2	1.0–1.4	Ref.	
Age																				
18–24 y	17/1993	0.9	0.5–1.3	2.3	0.8–6.7	29/1994	1.5	1.0–2.1	15.5	2.1–113.6	87/1929	4.5	3.7–5.5	4.3	2.3–8.0	54/1951	2.8	2.1–3.6	9.7	3.1–31.1
25–34 y	28/2658	1.1	0.7–1.5	2.8	1.0–8.0	21/2660	0.8	0.5–1.2	8.4	1.1–62.4	117/2599	4.5	3.8–5.4	4.3	2.3–7.9	63/2614	2.4	1.9–3.1	8.5	2.7–27.0
35–44 y	17/2341	0.7	0.5–1.2	1.9	0.7–5.7	10/2342	0.4	0.2–0.8	4.5	0.6–35.5	81/2285	3.5	2.9–4.4	3.4	1.8–6.3	29/2317	1.3	0.9–1.8	4.4	1.3–14.4
45–54 y	15/3697	0.4	0.2–0.7	1.1	0.4–3.2	7/3700	0.2	0.1–0.4	2.0	0.2–16.4	113/3609	3.1	2.6–3.8	3.0	1.6–5.5	31/3671	0.8	0.6–1.2	3.0	0.9–9.7
55–64 y	19/3105	0.6	0.4–1.0	1.6	0.6–4.8	2/3107	0.1	0.0–0.3	0.7	0.1–7.6	68/3039	2.2	1.8–2.8	2.1	1.1–4.0	23/3085	0.7	0.5–1.1	2.6	0.8–8.7
65+ y	4/1064	0.4	0.1–1.0	Ref.		1/1065	0.1	0.0–0.7	Ref.		11/1049	1.0	0.6–1.9	Ref.		3/1056	0.3	0.1–0.9	Ref.	
Highest professional degree																				
Poly-technic/university	56/6501	0.9	0.7–1.1	Ref.		21/6505	0.3	0.2–0.5	Ref.		206/6334	3.3	2.8–3.7	Ref.		77/6431	1.2	1.0–1.5	Ref.	
Vocational training	27/6548	0.4	0.3–0.6	0.5	0.3–0.8	24/6553	0.4	0.2–0.5	1.1	0.6–2.0	191/6423	3.0	2.6–3.4	0.9	0.8–1.1	65/6495	1.0	0.8–1.3	0.8	0.6–1.2
Current training	12/1476	0.8	0.5–1.4	0.9	0.5–1.8	20/1477	1.4	0.9–2.1	4.2	2.3–7.7	72/1431	5.0	4.0–6.3	1.5	1.2–2.0	50/1443	3.5	2.6–4.5	2.9	2.0–4.1
No training	1/103	1.0	0.1–6.6	1.1	0.2–8.1	2/103	1.9	0.5–7.4	6.0	1.4–25.3	4/100	4.0	1.5–10.2	1.2	0.5–3.2	6/98	6.1	2.8–13.0	5.1	2.3–11.5
Residence																				
<2000 inhabitants	14/2838	0.5	0.3–0.8	Ref.		14/2841	0.5	0.3–0.8	Ref.		94/2779	3.4	2.8–4.1	Ref.		43/2807	1.5	1.1–2.1	Ref.	
2000–20,000 inh.	31/5022	0.6	0.4–0.9	1.3	0.7–2.3	23/5024	0.5	0.3–0.7	0.9	0.5–1.8	161/4908	3.3	2.8–3.8	1.0	0.8–1.2	63/4970	1.3	1.0–1.6	0.8	0.6–1.2
20,000–100,000 inh.	21/3612	0.6	0.4–0.9	1.2	0.6–2.3	13/3616	0.4	0.2–0.6	0.7	0.3–1.5	106/3522	3.0	2.5–3.6	0.9	0.7–1.2	43/3567	1.2	0.9–1.6	0.8	0.5–1.2
100,000–500,000 inh.	12/1644	0.7	0.4–1.3	1.5	0.7–3.2	8/1644	0.5	0.2–1.0	1.0	0.4–2.3	59/1598	3.7	2.9–4.7	1.1	0.8–1.5	21/1623	1.3	0.8–2.0	0.8	0.5–1.4
>500,000 inh.	19/1476	1.3	0.8–2.0	2.6	1.3–5.2	11/1477	0.7	0.4–1.3	1.5	0.7–3.3	45/1445	3.1	2.3–4.1	0.9	0.6–1.3	26/1464	1.8	1.2–2.6	1.2	0.7–1.9
Donation service																				
Red Cross	72/10,845	0.7	0.5–0.8	1.0	0.6–1.7	51/10,851	0.5	0.4–0.6	1.0	0.5–1.8	363/10,606	3.4	3.1–3.8	1.2	0.9–1.5	144/10,729	1.3	1.1–1.6	0.7	0.5–1.0
University	15/2247	0.7	0.4–1.1	Ref.		11/2247	0.5	0.3–0.9	Ref.		64/2172	2.9	2.3–3.7	Ref.		41/2223	1.8	1.4–2.5	Ref.	
Private	11/1513	0.7	0.4–1.3	1.1	0.5–2.4	6/1515	0.4	0.2–0.9	0.8	0.3–2.2	43/1481	2.9	2.2–3.9	1.0	0.7–1.4	15/1490	1.0	0.6–1.7	0.5	0.3–1.0

Abbreviations: CI, confidence interval; FTD, first-time donor; PR, prevalence ratio; RD, repeat donor; Ref., reference; y, years.

TABLE 4 Prevalence ratios and 95% CI for demographic donor characteristics that are known at time of eligibility assessment and associated with non-compliance estimated in a multivariable Poisson regression model[a].

	Malaria risk	Body modification	Mild infection without fever	Febrile infection
Donor status	ni	ni	ni	ni
Sex	ni			ni
Female		4.9 (2.7–8.9)	1.3 (1.1–1.5)	
Male		Ref.	Ref.	
Age				
18–24 y	2.5 (1.2–5.1)	15.7 (3.7–65.7)	4.3 (2.2–8.3)	9.6 (3.0–30.6)
25–34 y	2.9 (1.5–5.6)	9.3 (2.2–39.6)	4.5 (2.4–8.6)	7.8 (2.5–25.0)
35–44 y	2.0 (1.0–4.2)	5.9 (1.3–26.7)	3.5 (1.8–6.7)	4.3 (1.3–14.1)
45–54 y	Ref.	2.6 (0.5–12.5)	3.1 (1.6–5.9)	2.7 (0.8–9.0)
55–64 y	1.7 (0.8–3.4)	-	2.2 (1.1–4.3)	2.3 (0.7–7.6)
65+ y	1.1 (0.4–3.3)	Ref.	Ref.	Ref.
Residence	ni	ni	ni	ni
Donation service	ni	ni		ni
Red Cross			1.4 (1.1–1.9)	
University			Ref.	
Private			1.1 (0.7–1.6)	

Abbreviations: CI, confidence interval; ni, not included; Ref., reference; y, years.
[a]Stepwise backward variable selection ($p < 0.05$).

testing (e.g., in the diagnostic window phase) or for which no routine testing is implemented (e.g., travel-related infection risks). Residual risk for possibly undetected (asymptomatic) infections is considered very low if deferrals are met.

In our compliance study, we found a considerable degree of non-compliance with deferral criteria for non-sexual exposures that may be associated with higher risk for transfusion-related transmission of pathogens. For all investigated issues, non-compliance depended on age, with significantly higher prevalence in donors younger than 35 years. Furthermore, women had significantly higher PRs for non-disclosure of recent body modifications and mild infections.

The observed relations of non-compliance to demographic characteristics of donors reflect the prevalence proportions of risk factors in the underlying population. For example, in Germany, tattoos and piercings are more common among women and among young adults (under 35 years) [5, 6]. As the personal perception of risk is essential for reporting a specific behaviour in the context of blood donations [7], consequently, non-compliance should be highest in these donor groups if invasive body modifications were perceived to be non-risky by this population [8].

Additionally, in women a tendency to over-report favourable behaviour and to be more prone to socially desirable responding is more common [9]. The somewhat more pronounced intention of women to help others with their blood donation compared to men [10] may also contribute to their more frequent non-disclosure of risk exposures.

The age-dependent non-compliance in our study is consistent with the observed higher non-disclosure of sexual risk exposures in donors younger than 35 years [3]. However, male and female donors differ in their compliance to sexual and non-sexual deferral criteria. Non-disclosure of sexual risks is more pronounced in male donors [3], whereas non-sexual risk exposures were less frequently indicated by women. Therefore, gender-specific donor education might help to reduce non-disclosure of risk exposures that are relevant for donor selection.

Incorrect recall and timing of relevant health risks may also contribute to non-compliance. However, there is no clear tendency towards underreporting of health issues—unbiased information, over-reporting as well as underreporting in certain recall periods is described [11–14]. Memory aids such as calendars improve the recall of travel and disease dates and may support the timing of health issues that are relevant for donor eligibility [15].

Furthermore, we found that donations at mobile services might be more prone to non-compliance with deferral criteria. In contrast to urban infrastructure with permanent access to blood donation centres, mobile services offer only a few donation appointments per year at suburban or rural locations. In consequence, motivated donors in rural areas cannot always choose a donation date that matches best with their risk-free periods. It should be noted that donors seem to be susceptible to non-disclosure of risks that they consider negligible in order not to miss their donation appointment. This could explain why non-disclosure of mild infection in the last week before donation was highest in BEs with mobile teams (Red Cross donation services).

The overall proportion of non-compliance is not insignificant; but it is difficult to quantify the impact of this non-compliance on related residual risks for infectious donations. Extrapolating the observed proportion of non-disclosed travel to malaria-endemic countries to the total donor population results in more than 10.000 donating

individuals per year in Germany who were probably at risk. Owing to an anti-Plasmodium antibody prevalence of 1.6% in deferred candidate donors in Switzerland and Germany [16] with travel to/living in malaria-endemic countries, possibly infectious donations cannot be excluded. Furthermore, the non-disclosure of travel may also increase the risk for other circulating transfusion-transmissible pathogens that are not tested for, for example, dengue virus or yellow fever virus. However, no arbovirus transmission and only one malaria transmission was reported to the German haemovigilance system since 1997, indicating an overall very low risk of transmission [17].

Because of the low residual risk, some deferral criteria are critically discussed, because temporary deferral of donors results in the drop-out of candidate donors [18–21] and requires increased efforts in motivation and reactivation of lapsed donors [22, 23]. Such reduced donor willingness could be an important issue in times of blood shortage. For example, the deferral of donors with new tattoos or piercings is questioned in some countries, as residual risk of transfusion-transmissible viral infections was not increased in recent studies [24, 25]. On the other hand, infection risks by tattooing still exists [26, 27]. Analysis of the reported HCV infections in the general population in Germany showed that of those infections with a reported transmission risk, 6% were attributed to tattooing and piercing in 2021 [28]. Therefore, the balance between protection of recipients and availability of blood products have to be carefully considered. This is true for all deferral criteria.

Moreover, the donor safety aspect of some deferral criteria has to kept in mind—a whole-blood donation during a mild infection is potentially unfavourable.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in Zenodo at https://zenodo.org/10.5281/zenodo.10451630.

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