

Undisclosed Sexual Risk Exposures: Results of a Nationwide Compliance Study among Whole Blood Donors in Germany

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Keywords

Blood donors · Non-compliance · Sexual infection risks · MSM

Abstract

Background: Undisclosed sexual infection risks are the main reasons for transfusion transmissible infections in German blood donors that have qualified for donation by donor health interviews and questionnaires. Until now, data about compliance with deferral criteria were only available from post-donation interviews with infected donors, and information about the proportion of donors which did not disclose (sexual) risks at the donor health questionnaire was not available. **Methods:** A prospective nationwide anonymous online survey was conducted to investigate compliance of whole blood donors with deferral criteria for sexual infection risks. Twenty-one blood establishments which represent 80% of the regular whole blood-donor population invited all donors which donated blood during an 8-week period between January and March 2020. **Results:** 14,882 participants completed the questionnaire. A relevant proportion of non-compliance was shown (3.0%, 95% CI: 2.7–3.3%) – with male donors being non-compliant significantly more frequently than females (3.5% vs. 2.2%, $p < 0.001$). A quarter of the non-compliant men were MSM (0.9%, 95% CI: 0.7–1.1%). Non-compliance was strongly associated with the perception that questions about sexual risk exposures are too private. This is in line with the finding that a large proportion of donors (21%) refused to answer at least one question about

sexual infection risks. **Conclusion:** The presented data, collected for the first time, is suitable for assessing the impact of changes in the donor selection process. Donor's limited willingness to provide detailed information about sexual risk behaviour has to be kept in mind when further strategies for fair appraisal of individual sexual infection risks will be discussed.

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Introduction

In addition to routine screening of blood donations for transfusion transmissible pathogens, the safety of blood products can be most reliably ensured if persons with underlying risk of undetectable (window period) infections are deferred from donating. For this purpose, appropriate donor selection criteria have to be established. Recording and assessment of sexual infection risks is of particular importance as undetected sexually transmissible infections may cause severe disease in recipients of blood products (e.g., HIV, hepatitis B). Candidate donors with recent sexual risk exposures are therefore deferred from donation.

In Germany, guidelines for donor selection have been changed in 2017. Since then, the permanent deferral of persons with high sexual infection risks was reduced to a 12-month-deferral for men who have sex with men (MSM), heterosexuals with sexual risk behaviour (e.g., frequently changing sexual partners), sex workers, and

transsexual persons with sexual risk behaviour. Furthermore, a 4-month-deferral exists for heterosexual donors that had sexual intercourse with a person mentioned above or a partner from a country where HIV or hepatitis is epidemic.

For recording of sexual risk exposures, in Germany, blood donors have to complete a donor health questionnaire (DHQ) at each donation. The use of an evaluated uniform DHQ [1] is recommended by the National Advisory Committee Blood; however, it is not mandatory. Afterwards, a physician assesses eligibility for blood donation in a personal interview. All donors must be given a confidential opportunity to state whether their donation can be used or should be excluded from further processing (confidential self-exclusion). However, donors' compliance with the deferral criteria, i.e., their complete and correct answers to questions on risk exposures is a key factor for prevention of window period donations.

Compliance of donors with deferral criteria for sexual risk behaviour has been investigated intensively – especially non-compliance with MSM policies [2–7]. Non-compliance was mainly found to be associated with incorrect perception of personal risks, personal/intimate character of questions, and – in case of MSM deferral – rejection of different deferral policies based on sexual orientation. So far, a systematic investigation of overall non-compliance with donor selection criteria is missing in Germany, but the analysis of data from post-donation interviews for sexually transmissible infection risks showed that most of the infected donors in Germany would not have been allowed to donate if they had completely disclosed their risk exposures [8].

Therefore, we conducted a nationwide anonymous online survey among whole blood donors to estimate the extent of non-compliance with deferral criteria for sexual risk exposures. Additionally, we investigated sociodemographic as well as donation-related factors that were associated with non-compliance.

Materials and Methods

Recruitment of Participants

As estimation of MSM non-compliance was the main focus of the study, sample size was calculated with Cochran's formula [9] for an assumed prevalence of 1.5% detectable in the smallest male donor group (35–44 years). The assumption was based on reported MSM non-compliance in the Dutch donor population [10] that should be similar to the German situation as underlying characteristics of the general MSM populations are comparable [11]. For estimation of the assumed prevalence with a 95% confidence limit and $\pm 30\%$ accuracy, 2,270 men in the age group 35–44 years were required. Considering the sex and age distribution of the German donor population, the aim was to include altogether 28,400 donors in the study.

We invited all German blood establishments (BEs) that collect whole blood donations to support the study. BEs were asked to invite all non-deferred donors within an 8-week period between

January and March 2020 by handing over a leaflet after a successful donation. The 8-week period was chosen to avoid multiple inclusion of repeat whole blood donors. To encourage donors to participate in the study and to disclose potential risk behaviour truthfully, we conducted an anonymous survey and pointed out specifically that answers could neither be linked to the donor nor reported back to the BE and would therefore not have any impact on their donor career. BE provided numbers of invited donors stratified for age, sex, and donor status (new donors, repeat donors) for a response analysis.

Survey Questions

The survey questionnaire contained 31 major questions about sociodemographic characteristics (age, sex, size of residence, highest professional degree, donor status, last BE), last donation process (i.e., satisfying donor education, clarity of questions, privacy during pre-donation health assessment, confidential self-exclusion), sexual risk behaviour, and data about further deferral conditions (i.e., recent fever, travel, tattoo). As skipping of answers was allowed for several questions, a complete questionnaire was defined if the last question of the survey had been reached. The average completion time was 7 min. As the study has focused on compliance with selection criteria for persons with an increased risk for sexually transmitted infections, sexual risk behaviour was identified in accordance to the haemotherapy guidelines [12] as follows:

1. persons who had sex with a partner from a country where HIV or hepatitis is endemic (HHEC) within 4 months prior to donation,
2. persons who had been paid for sex within 12 months prior to donation,
3. persons who paid for sex within 4 months prior to donation,
4. men who had sex with a man within 12 months prior to donation,
5. women who had sex with a bisexual man within 4 months prior to donation,
6. persons with frequently changing sex partners within 12 months prior to donation.

Additionally, condom-less sex with a new partner within 4 months prior to donation was recorded because it is discussed as gender-blind indicator for sexual risk behaviour. Further questions about use of condoms were asked to determine the willingness to provide detailed information about sexual behaviour. The online questionnaire was developed using the software VOXCO online version 6.0.

Assessment of Non-Compliance

Non-compliance was quantified for both MSM and heterosexual risk exposures according to the criteria given above. Heterosexual persons who had more than three sexual partners within the last 12 months were classified to have had frequently changing sex partners corresponding to risk recording in the German uniform donor health questionnaire [13].

Prevalence of non-compliance is given with 95% confidence intervals (95% CI). Prevalence estimates were post-stratified for sex and age group considering the cluster sampling in BE using data about invited blood donors to check the representativeness of study results. Association of non-compliance with sociodemographic data and specific aspects of the donation process was assessed using modified Poisson regression with robust error estimation [14] providing prevalence ratios in a univariate analysis.

Moreover, donation aspects that were associated with non-compliance were determined using multivariable models stratified/adjusted for potential confounders that were identified as minimal sufficient adjustment set based on hypothesized causal relationships using a directed acyclic graph (see below). The mul-

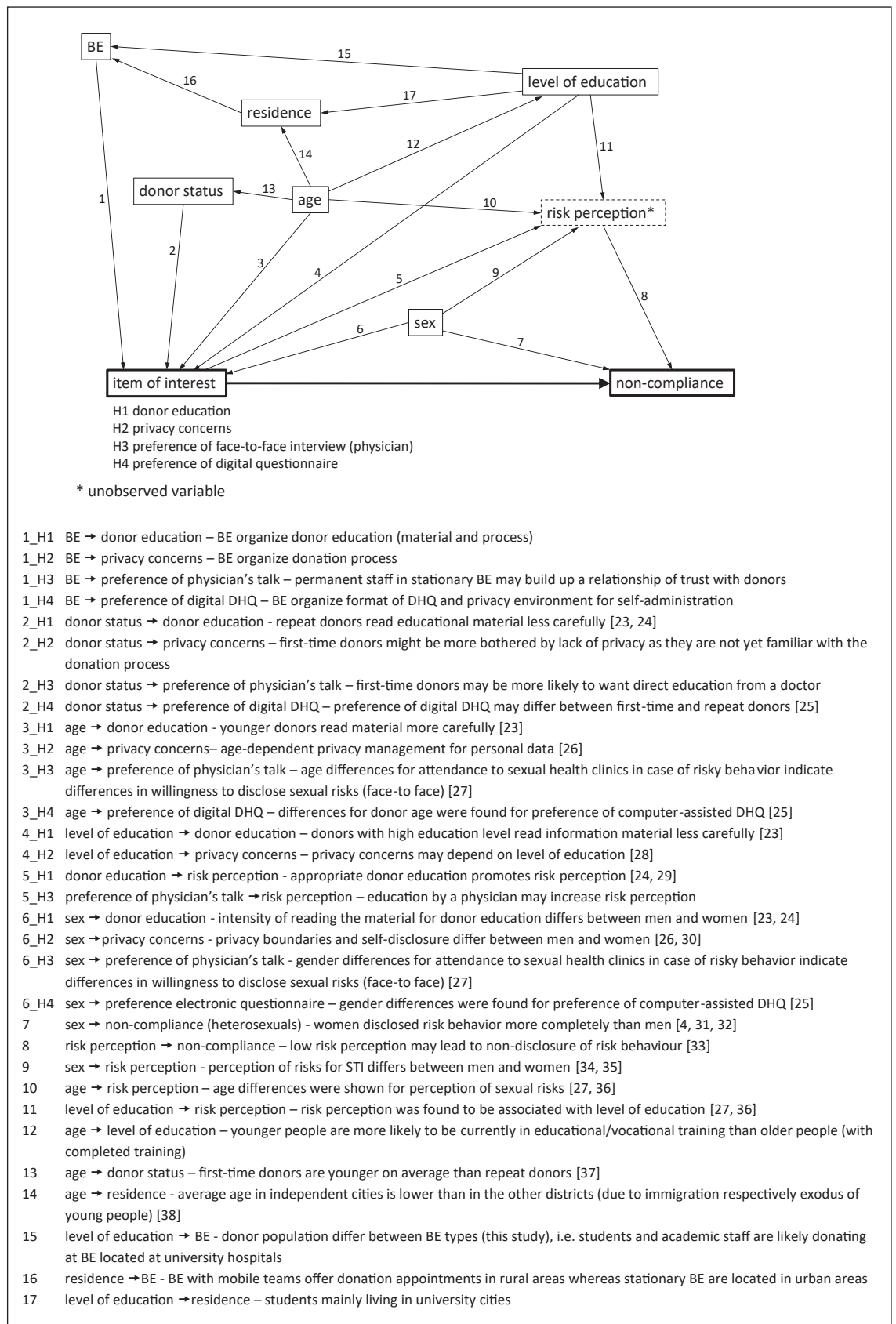


Fig. 1. Directed acyclic graph (causal diagram). Visualization of relationships between donation aspects and non-compliance considering various co-factors. Underlying associations are described for each path. Variable set consisting of sex, age, and grade of occupational education was identified as minimal sufficient adjustment set. STI, sexually transmissible infection.

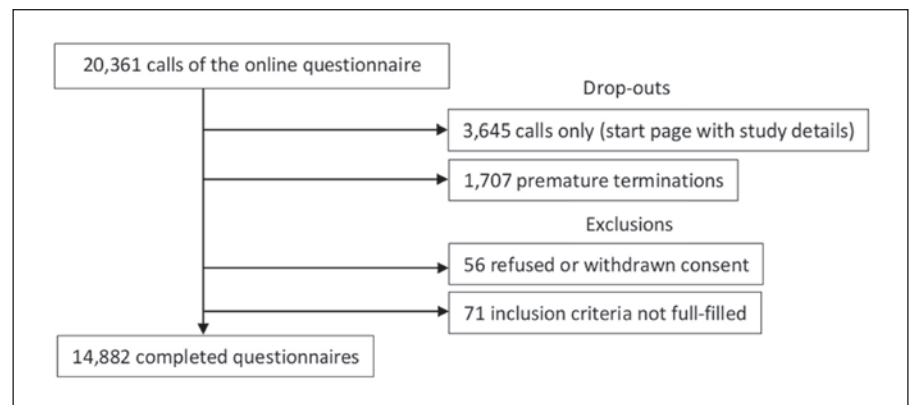


Fig. 2. Participation. Flow of participating donors.

tivariable models were built using a stepwise backward elimination approach with a p level threshold of 0.05 where the base model contained all donation aspect variables. Statistical analyses were performed with Stata 15 software.

Directed Acyclic Graphs

Multivariable models were often used to determine factors that were most likely to be associated with non-compliance (variable selection) and/or to quantify the relationship between donor or donation characteristics and non-compliance. Mostly, variables that were significantly associated with non-compliance in univariate regression models ($p < 0.05$) were considered in multivariable models and “adjusted” estimates were reported. However, it was shown that adjustment for variables that were chosen solely on statistical criteria may create invalid estimates [15].

Adjustment for covariates in models that investigate a probable causal effect of exposures on certain outcomes (i.e., non-compliance) is advised for variables that are associated with the exposure as well as with the outcome – so called confounders. Otherwise, the “real” effect of the independent variable (exposure) may be obscured. On the other hand, analytical adjustment for covariates may introduce bias where no confounding exists [16], e.g., when intermediate variables or their descendants were used for adjustment.

Therefore, knowledge of the underlying causal structure is essential for accurate determination of confounders and valid effect estimation. Causal diagrams are suggested as graphical approach for analysis of confounding [16] and therefore we constructed a directed acyclic graph (“causal diagram”) to visualize the hypothesized causal structure of donor/donation factors and non-compliance (Fig. 1). The relationships displayed in the graph were based on statistical associations identified in epidemiological studies, official statistics, or, if the former was lacking, plausible assumptions. The absence of a directed path between variables indicated that we believe there is no direct effect of one variable on the other. We then deduced the minimally sufficient adjustment set to minimize bias using the graphical interface DAGitty [17]. Multivariable models created with this method were used to estimate the effect of different donation aspects on non-compliance in our study population based on the following hypotheses:

- H1: Donor education perceived as insufficient reinforces non-disclosure of sexual health [18].
- H2: Privacy concerns reinforce non-disclosure of sexual health risks [19].
- H3: Physician consultation on sexual risks can encourage disclosure of sexual risks [20].
- H4: Computer-assisted instead of paper-based questionnaires support compliance [21, 22].

Table 1. Demographic data of the study population ($n = 14,882$) from 21 BE

| | <i>n</i> (%) |
|-------------------------------|---------------|
| Donor status | |
| New donors | 455 (3.1) |
| Repeat donors | 14,426 (96.9) |
| Sex | |
| Female | 5,555 (37.3) |
| Male | 9,327 (62.7) |
| Age | |
| 18–24 years | 1,994 (13.4) |
| 25–34 years | 2,660 (17.9) |
| 35–44 years | 2,344 (15.8) |
| 45–54 years | 3,709 (24.9) |
| 55–64 years | 3,110 (20.9) |
| 65+ years | 1,065 (7.2) |
| Highest professional degree | |
| Polytechnic/university degree | 6,512 (43.8) |
| Vocational training | 6,557 (44.1) |
| Current training | 1,477 (9.9) |
| No training | 103 (0.7) |
| Residence | |
| <2,000 inhabitants | 2,841 (19.1) |
| 2,000–20,000 inh | 5,026 (33.8) |
| 20,000–100,000 inh | 3,619 (24.3) |
| 100,000–500,000 inh | 1,647 (11.1) |
| >500,000 inh | 1,481 (10.0) |

Results

Initially twenty-three BE supported the study which represent approximately 80% of the German donor population. Data related to two BE were excluded because an invitation of deferred donors could not be ruled out completely (violation of inclusion criterion).

Participants

Initially, 20,361 donors called the survey homepage. Eighteen per cent of them did not start the survey after reading detailed study information. Further 11% of the donors were excluded from the analysis due to refused or withdrawn consent, violation of inclusion criterion, or prema-

Table 2. Invited donor population from the subset of 19 BE that provided invitation data and related participants with complete questionnaires

| | Invited donors, n (%) | Participants, n (%) | Invited male donors, n (%) | Male participants, n (%) |
|-------------|-----------------------|---------------------|----------------------------|--------------------------|
| Sex | | | | |
| Female | 123,366 (42.4) | 4,514 (37.3) | | |
| Male | 167,468 (57.6) | 7,770 (62.7) | | |
| Age | | | | |
| 18–24 years | 44,787 (15.4) | 1,704 (13.9) | 21,056 (12.6) | 773 (9.9) |
| 25–34 years | 49,406 (17.0) | 2,241 (18.2) | 29,593 (17.7) | 1,346 (17.3) |
| 35–44 years | 41,205 (14.2) | 1,882 (15.3) | 24,064 (14.4) | 1,204 (15.5) |
| 45–54 years | 67,463 (23.2) | 3,022 (24.6) | 38,748 (23.1) | 1,950 (25.1) |
| 55+ years | 87,973 (30.2) | 3,435 (28.0) | 54,007 (32.2) | 2,497 (32.1) |

ture termination of the survey questionnaire. Altogether 14,882 complete questionnaires were analysed (Fig. 2).

Most of the study population were repeat donors ($n = 14,426$; 97%) and were male ($n = 9,327$; 63%). Median age of the participants was 46 years. Sociodemographic details are given in Table 1.

Invited Donors: Response Analysis

A response analysis could be performed for a subset of 19 BE which provided invitation data. 290,834 donors were invited in these 19 BE, 123,366 female (42%) and 167,468 male donors (58%). 12,284 of the participants with complete questionnaires could be assigned to the respective BE. According to the standard definitions of the AAPOR [38], this corresponds to a minimum response rate RR1 of 4.2%.

We did not find substantial bias regarding sex and age distribution between the participants and the invited donor population (Table 2). BE-specific response rates varied between 1% and 21% and were mostly higher in hospital-based BE compared to BE with mobile/temporary donation sites or branches.

Compliance with Deferral Criteria for Sexual Risk Exposures

Men Who Have Sex with Men

Of the 9,284 male donors with data about MSM behaviour, 246 (2.6%, 95% CI: 2.3–3.0%) stated that they ever had sex with a man and one third of them ($n = 80$, 0.9%, 95% CI: 0.7–1.1%) disclosed sex with a man within the last 12 months prior to donation (non-compliant MSM). Prevalence of non-compliant MSM was highest among donors younger than 35 years. We identified 14 non-compliant MSM younger than 25 years (1.6% of the male donor population in this age group), 29 in the age group 25–34 years (1.8%), 15 in each group 35–44 years (1.0%) and 45–54 years (0.6%), and 7 in the age group 55–64 years (0.3%) (Table 3). Fifty-four non-compliant MSM had more than one sexual partner within the last 12 months, 14 reported condomless sex with a new partner within the last 4 months, and 5 had been paid for sex

within the last 12 months. All non-compliant MSM were repeat donors. Six non-compliant MSM indicated the use of confidential self-exclusion. Adjusting the estimate of MSM non-compliance to the age distribution of the invited male donor population did not change the prevalence estimate (0.9%, 95% CI: 0.6–1.4%).

Twenty of the non-compliant MSM (25%) did not feel well educated about the need for data collection about sexual risk exposures, 13 (16%) indicated missing privacy, and 10 (13%) would prefer a conversation with a physician about sexual risk exposures instead of a self-completed questionnaire. Thirty-five non-compliant MSM (44%) classified questions about sexual risk behaviour as too personal. In univariate analyses, non-compliance of MSM was found to be significantly higher in age groups <45 years compared to donors aged 55–64 years, in donors with current vocational/academic training compared to donors with polytechnic or university degree, in donors living in metropolitans compared to donors from rural residences, and for donation at a university service compared to donation at Red Cross services (Table 3). Considering the potential confounding effects of age and level of occupational education missing a perception that questions about sexual risks are too personal was related to a higher prevalence of non-compliance in a multivariable model (Table 4).

Heterosexual Risk Exposures

Most common undisclosed risk exposure was sex with >3 partners within the last 12 months prior to donation what is used as indication for sex with frequently changing partners. Seventy-five female (1.4% of all females; 95% CI: 1.1–1.7%) and 152 male (1.6% of all males; 95% CI: 1.4–1.9%) donors have disclosed the exposure. Among BE which asks for sex with frequently changing partners instead of sex with >3 partners, significantly more donors disclosed sex with >3 partners (87/4,355 vs. 140/10,396, χ^2 test $p = 0.003$).

Sex with a partner from an HIV and/or hepatitis endemic country within the last 4 months before donation was reported by 44 female and 65 male donors. Sex with a

Table 3. Proportion of non-compliance in certain donors and univariate analysis of association between donor demographics/donation aspects and non-compliance

| | Heterosexual risks | | | | | | | | Active MSM | | | |
|--|--------------------|----------|-------------|-------------------|-------------|----------|-------------|------------------|-------------|----------|-------------|-------------------|
| | female donors | | | | male donors | | | | male donors | | | |
| | % | 95% CI | PR | 95% CI | % | 95% CI | PR | 95% CI | % | 95% CI | PR | 95% CI |
| Donor demographics | | | | | | | | | | | | |
| Age group | | | | | | | | | | | | |
| 18–24 years | 4.5 | 3.3–5.8 | 5.16 | 1.26–21.08 | 4.4 | 3.2–6.0 | 3.70 | 1.86–7.36 | 1.6 | 0.9–2.6 | 4.86 | 1.97–12.00 |
| 25–34 years | 4.3 | 3.1–5.6 | 4.94 | 1.21–20.21 | 5.2 | 4.1–6.4 | 4.30 | 2.24–8.25 | 1.8 | 1.2–2.6 | 5.68 | 2.49–12.93 |
| 35–44 years | 1.3 | 0.6–2.3 | 1.50 | 0.34–6.73 | 2.8 | 2.0–3.7 | 2.31 | 1.16–4.59 | 1.0 | 0.6–1.7 | 3.10 | 1.27–7.60 |
| 45–54 years | 0.7 | 0.3–1.3 | 0.77 | 0.17–3.53 | 1.9 | 1.4–2.5 | 1.57 | 0.79–3.11 | 0.6 | 0.4–1.1 | 1.99 | 0.81–4.86 |
| 55–64 years | 0.6 | 0.2–1.4 | 0.75 | 0.15–3.68 | 1.3 | 0.9–1.9 | 1.07 | 0.52–2.20 | 0.3 | 0.1–0.7 | Ref | |
| 65+ years | 0.9 | 0.1–3.1 | Ref | | 1.2 | 0.6–2.2 | | | – | | – | |
| Education level | | | | | | | | | | | | |
| Polytechnic/university degree | 2.6 | 2.0–3.4 | Ref | | 2.6 | 2.2–3.1 | Ref | | 0.7 | 0.5–1.0 | Ref | |
| Vocational training | 1.2 | 0.8–1.7 | 0.45 | 0.29–0.70 | 2.3 | 1.8–2.9 | 0.87 | 0.66–1.15 | 0.8 | 0.5–1.1 | 1.14 | 0.69–1.87 |
| Current training | 4.5 | 3.2–6.2 | 1.73 | 1.14–2.62 | 4.9 | 3.4–6.9 | 1.90 | 1.30–2.77 | 2.3 | 1.3–3.8 | 3.39 | 1.86–6.16 |
| No training | 4.6 | 0.6–15.8 | 1.77 | 0.45–7.04 | 5.1 | 1.1–14.1 | 1.96 | 0.64–5.98 | 1.7 | 0.04–8.9 | 2.40 | 0.33–17.33 |
| Residence | | | | | | | | | | | | |
| <2,000 inhabitants | 1.6 | 1.0–2.5 | Ref | | 1.9 | 1.3–2.6 | Ref | | 0.8 | 0.4–1.4 | Ref | |
| 2,000–20,000 inh | 1.7 | 1.1–2.4 | 1.03 | 0.58–1.85 | 2.3 | 1.8–2.9 | 1.23 | 0.82–1.86 | 0.5 | 0.3–0.8 | 0.65 | 0.32–1.31 |
| 20,000–100,000 inh | 2.2 | 1.4–3.1 | 1.34 | 0.74–2.42 | 2.9 | 2.3–3.7 | 1.57 | 1.04–2.38 | 1.0 | 0.7–1.5 | 1.25 | 0.65–2.41 |
| 100,000–500,000 inh | 2.7 | 1.5–4.3 | 1.67 | 0.86–3.25 | 3.4 | 2.3–4.6 | 1.79 | 1.12–2.88 | 0.8 | 0.3–1.5 | 0.94 | 0.39–2.23 |
| >500,000 inh | 5.0 | 3.4–7.0 | 3.08 | 1.73–5.47 | 3.5 | 2.4–4.9 | 1.86 | 1.14–3.04 | 1.7 | 1.0–2.8 | 2.11 | 1.02–4.35 |
| BE | | | | | | | | | | | | |
| Red Cross | 1.7 | 1.3–2.1 | Ref | | 2.1 | 1.8–2.5 | | | 0.6 | 0.4–0.8 | Ref | |
| University service | 3.2 | 2.2–4.6 | 1.91 | 1.25–2.92 | 4.4 | 3.4–5.7 | 2.07 | 1.53–2.80 | 2.2 | 1.5–3.2 | 3.69 | 2.30–5.91 |
| Other | 4.1 | 2.6–6.1 | 2.43 | 1.52–3.91 | 3.3 | 2.3–4.6 | 1.54 | 1.06–2.25 | 0.8 | 0.4–1.6 | 1.37 | 0.64–2.91 |
| Aspects of donation | | | | | | | | | | | | |
| Appropriate donor education | | | | | | | | | | | | |
| Yes | 2.1 | 1.7–5.0 | Ref | | 2.4 | 2.1–2.8 | Ref | | 0.8 | 0.6–1.0 | Ref | |
| No | 3.0 | 1.9–4.5 | 1.45 | 0.93–2.27 | 3.9 | 2.9–5.1 | 1.64 | 1.21–2.22 | 1.5 | 0.9–2.4 | 2.04 | 1.23–3.37 |
| Appropriate privacy | | | | | | | | | | | | |
| Yes | 2.0 | 1.6–2.4 | Ref | | 2.5 | 2.2–2.9 | Ref | | 0.8 | 0.6–1.0 | Ref | |
| No | 4.5 | 2.9–6.8 | 2.28 | 1.45–3.58 | 3.7 | 2.4–5.3 | 1.44 | 0.96–2.17 | 1.9 | 1.0–3.2 | 2.40 | 1.33–4.32 |
| Too personal questions | | | | | | | | | | | | |
| Yes | 6.1 | 3.5–9.7 | 3.03 | 1.82–5.05 | 5.1 | 3.6–7.0 | 2.10 | 1.48–2.98 | 5.0 | 3.5–6.9 | 9.72 | 6.28–15.05 |
| No | 2.0 | 1.6–2.4 | Ref | | 2.4 | 2.1–2.8 | Ref | | 0.5 | 0.4–0.7 | Ref | |
| Preference of medical consultation | | | | | | | | | | | | |
| Yes | 6.7 | 4.0–10.5 | 3.36 | 2.04–5.51 | 5.8 | 4.0–8.1 | 2.41 | 1.68–3.46 | 1.8 | 0.9–3.3 | 2.25 | 1.17–4.34 |
| No | 2.0 | 1.6–2.4 | Ref | | 2.4 | 2.1–2.8 | Ref | | 0.8 | 0.6–1.0 | Ref | |
| Preference of electronic questionnaire | | | | | | | | | | | | |
| Yes | 2.9 | 1.5–5.1 | 1.34 | 0.73–2.47 | 3.9 | 2.8–5.3 | 1.59 | 1.14–2.23 | 1.3 | 0.7–2.2 | 1.60 | 0.89–2.89 |
| No, indifferent | 1.9 | 1.3–2.7 | Ref | | 2.4 | 1.9–3.0 | Ref | | 0.6 | 0.3–0.9 | Ref | |

Significant differences compared to the reference are given in bold ($p < 0.05$).

sex worker within 4 months before donation was reported only by men ($n = 82$). Two female and 11 male donors have been paid for sex within 12 months prior to donation. Sex with a bisexual man was reported by 10 women. Corresponding proportions are shown in Figure 3.

Altogether 365 donors (2.5%, 95% CI: 2.2–2.7%) have reported heterosexual risk exposures that would have led to deferral – 123 female (2.2%, 95% CI: 1.8–2.6%) and 242 male donors (2.6%, 95% CI: 2.3–3.0%). Post-stratification did not change the prevalence estimates substantially: total non-compliance with heterosexual risk deferral 2.3% (95% CI: 1.8%–3.0%), non-compliance of female donors 2.1% (95% CI: 1.7%–2.6%), non-compliance of male donors 2.5% (95% CI: 1.8%–3.5%).

Non-compliance with heterosexual selection criteria was most abundant among young donors: more than half

of the non-compliant heterosexual donors ($n = 214$) were younger than 35 years representing 4.7% (95% CI: 4.1–5.3%) of all participants in this age group (Table 3). Donor education was perceived as insufficient by 74 of the non-compliant heterosexual donors (20%), 47 reported missing privacy (13%), and 51 classified recording of sexual risk exposures as too private (14%).

Twelve non-compliant heterosexual donors indicated the use of confidential self-exclusion. Prevalence of non-compliance in certain donor groups is given in Table 3. In univariate analyses, a significantly higher prevalence of non-compliance regarding deferral criteria for heterosexual risk exposures was found in both female and male donors for age groups <35 years compared to 65+ years, current vocational training compared to polytechnic or university degree, residence in a metropolitan compared

Table 4. Prevalence ratios for aspects of donation that are associated with non-compliance estimated in a multivariable Poisson regression model* adjusted for age and grade of occupational education

| | Heterosexual risks | | | | Active MSM | |
|--|--------------------|-----------|-------------|-----------|-------------|------------|
| | female donors | | male donors | | male donors | |
| | aPR | 95% CI | aPR | 95% CI | aPR | 95% CI |
| Too personal questions | | | | | | |
| Yes | 2.83 | 1.70–4.71 | 1.98 | 1.37–2.84 | 9.70 | 6.21–15.15 |
| No | Ref | | Ref | | Ref | |
| Preference of medical consultation | | | | | | |
| Yes | 2.01 | 1.19–3.39 | 1.85 | 1.27–2.70 | ni | |
| No | Ref | | Ref | | | |
| Privacy | | | | | | |
| Yes | Ref | | ni | | ni | |
| No | 1.94 | 1.23–3.03 | | | | |
| Appropriate donor education | ni | | ni | | ni | |
| Preference of electronic questionnaire | ni | | ni | | ni | |

ni, not included. * Stepwise backward variable selection ($p < 0.05$).

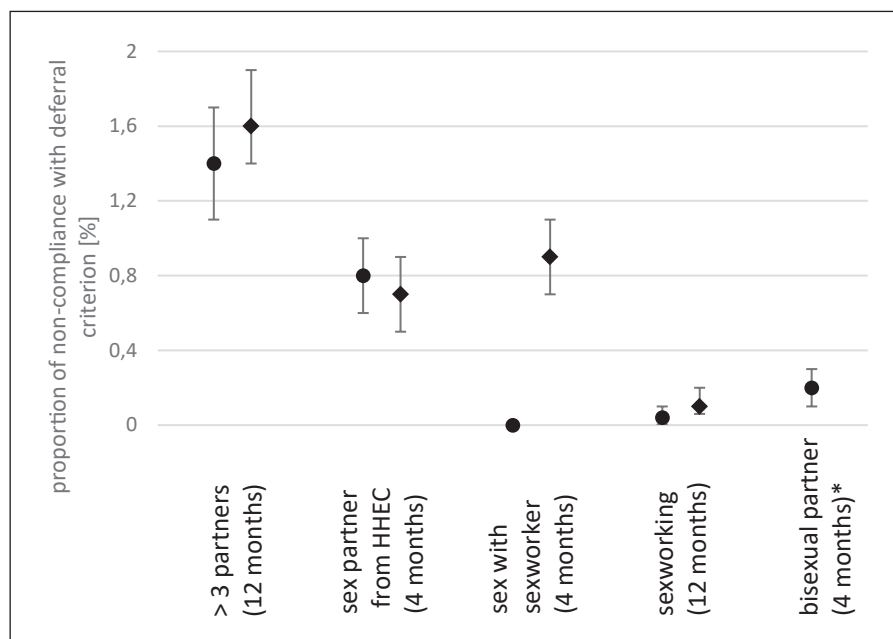


Fig. 3. Non-compliance with heterosexual risk criteria. Proportion of non-compliant female and heterosexual male donors with several sexual risk exposures (incl. 95% CI). *Female donors only, circles – female donors, diamonds – heterosexual male donors.

to rural residence, and donation in a service other than Red Cross service compared to Red Cross service.

Among female donors, missing of privacy, perception that questions about sexual risks are too personal, and the preference of a medical consultation for recording of sexual risks instead of a questionnaire were associated with non-compliance in a multivariable model adjusted for the possible confounding effect of age and level of occupational education. In male donors, a higher prevalence was found for perception that questions about sexual risks are too personal and the preference of a medical consultation for recording of sexual risks instead of a questionnaire (Table 4).

Gender-Blind Indicators for Sexual Risk Exposures

A new sexual partner within 4 months before last donation (no deferral criterion so far) was reported by 721 donors (4.8%, 95% CI: 4.5–5.2%) without prevalence differences between female and male donors but with strong age-dependency: 18–24 years 236/1,981 donors (11.9%, 95% CI: 10.5–13.4%), 25–34 years 264/2,654 donors (9.9%, 95% CI: 8.8–11.1%), 35–44 years 105/2,334 donors (4.5%, 95% CI: 3.7–5.4%), 45–54 years 76/3,678 donors (2.1%, 95% CI: 1.6–2.6%) 55–64 years 29/3,076 donors (0.9%; 95% CI: 0.6–1.4%), 65+ years 11/1,056 donors (1.0%, 95% CI: 0.5–1.9%). Of donors with a new partner,

209 were non-compliant with at least one deferral criterion for sexual risks. Unprotected sexual intercourse with a new partner within 4 months prior to donation (no deferral criterion so far) was reported by 276 participants (1.9%, 95% CI: 1.6–2.1%) – among them 77 non-compliant donors. No differences were found between women and men, but condomless sex with a new partner was clearly age-dependent: 18–24 years 90/1,981 donors (4.5%, 95% CI: 3.7–5.6%), 25–34 years 88/2,654 donors (3.3%, 95% CI: 2.7–4.1%), 35–44 years 47/2,334 donors (2.0%, 95% CI: 1.5–2.7%), 45–54 years 35/3,678 donors (1.0%, 95% CI: 0.7–1.3%) 55–64 years 10/3,076 donors (0.3%; 95% CI: 0.2–0.6%), 65+ years 5/1,056 donors (0.5%, 95% CI: 0.2–1.1%).

Non-Response to Questions about Sexual Risk Behaviour

Non-response to questions about sexual risk exposures that are relevant for donor selection was found for 157 donors (1.1%, 95% CI: 0.9–1.2%) – 55 female (1.0%, 95% CI: 0.7–1.3%) and 102 male donors (1.1%, 95% CI: 0.9–1.3%). Further questions about condom usage have been skipped by 3,054 donors – so a total of 3,111 donors (21%, 95% CI: 20–22%) have skipped at least one question about sexual behaviour. We did not find relevant differences between first and repeat donors (19% vs. 21%), male and female donors (21% vs. 20%), and regarding the highest professional degree.

Significant differences were found between age groups with a clear rise between age group 25–34 years (7.7%) and 65+ years (41%). Non-response in the age group 18–24 years was 14%.

Looking at prematurely terminated questionnaires ($n = 1,707$), we found 958 terminations (56%) during questions about sexual risk exposures. This accounts for 5.8% of all started questionnaires. For comparison reasons, highest non-response rates for questions non-related to sexual behaviour were 1.6% (95% CI: 1.4–1.8%) when asking about sociodemographic characteristics (highest professional degree) and 0.2% (95% CI: 0.1–0.2%) on questions about non-sexual infection risks (drug use).

Discussion/Conclusions

Recording of sexual risk behaviour for assessment of donor eligibility and minimization of residual infection risks for blood recipients is challenging: (I) Respective questions touch very intimate areas of life and not all people are willing to answer with the necessary openness. It was shown that questions about sexual behaviour lead to a relevant proportion of non-response in health surveys – especially in studies that focus on general health topics rather than sexual health [39]. In a validation study of a draft European standard DHQ, it was found that people

would answer questions on sexual risk behaviour less honestly than questions on other selection criteria [40]. Furthermore, more than 40% of blood donors in a large local BE declared questions on sexual risks as too personal [41].

(II) Deferral criteria for sexual infection risks base on assessment of population groups with increased risk, i.e., sex workers or MSM, in most countries. Therefore, donor selection is sometimes perceived as discriminatory and it is documented that dissatisfaction of donors with deferral criteria may result in non-compliance. For example, refusal of differences based on sexual orientation was the main reason (58%) for non-compliance of MSM in the French Complidon study [6]. In The Netherlands, more than a quarter of non-compliant MSM did not disclose their risk due to perceived discrimination [10].

In consequence, incomplete disclosing of sexual risk exposures may weaken blood safety as undetectable transfusion transmissible infections could enter the blood supply. Therefore, underlying non-compliance has to be taken into account in residual risk appraisal especially when policy changes are considered. This is the first study to quantify non-compliance of whole blood donors with deferral criteria for sexual risk behaviour in Germany.

Altogether, we found a relevant proportion of non-compliance among whole blood donors (3.0%) – with male donors being non-compliant significantly more frequently than females (3.5% vs. 2.2%, $p < 0.001$). A quarter of the non-compliant men were MSM resulting in a relatively small percentage of male donors which did not disclose their MSM activity within the last 12 months before their last donation (0.9%). This proportion is in line with (but somewhat higher than) other reported non-compliance with a 12 months deferral period of MSM in Australia, Canada, France, Hong Kong, and the UK (0.23%–0.73% [2, 5–7, 42]). Not surprisingly, a disproportionate share was found among men younger than 35 years what significantly entails the observed correlation between MSM non-compliance and current vocational/academic training. Despite the small proportion, an estimated number of 13,000 non-compliant MSM is donating every year – based on age-weighted extrapolation to the German male donor population. This is far more than the expected annual number of non-compliant MSM in Canada (except Quebec; $n = 533$ [5]) and the UK ($n = 3,030$ [2]) during the 12-month-deferral policy. Due to the large absolute number alone, there is a risk of (undetectable) infections as long as not only MSM with low infection risks are donating. Because risky sexual behaviour was reported by non-compliant MSM in our study, e.g., condom-less sex with a new partner and sex working, it is important to identify factors which are associated with non-compliance and to implement countermeasures.

Perceiving questions about sexual risk behaviour as too private is a strong (and the only) predictor for non-compliance of active MSM when adjusted for potential confounders. In our study, the discomfort with such questions (44% of non-compliant MSM) was clearly more pronounced compared to studies in France (16% [6]), the UK (19% [2]), and the Netherlands (27% [10]). In Australia, the association of refusal of personal questions and non-compliance was similarly pronounced among MSM as in our study [7]. Due to the remarkable share of discomfort with sexual risk questions and indications that outing during blood donation seems to be a relevant barrier for disclosure of male-to-male sex [10], reasons for non-compliance of MSM should be further investigated in detail. This is particularly necessary because more detailed recording of sexual risks is introduced in Germany that allows the identification and blood donation of MSM with low infection risk and shortening of deferral periods.

Non-compliance with heterosexual risk criteria was associated with perceiving questions as too private in both female and male donors, too. However, the association was less strong than in MSM.

Furthermore, non-compliant heterosexual donors would have preferred a direct conversation with a physician about sexual risk exposures instead of a self-completed questionnaire significantly more often. This is probably an indication for both a reluctance to self-assess the own risk exposures and the desire to have the (neutral) assessment done by a physician. Although most studies have shown that self-administered questionnaires were superior to face-to-face interviews regarding complete recording of sexual risks [43], personal conversation may improve disclosure in the context of blood donation. This finding highlights the importance of the presence of trustworthy staff which should be actively involved in recording of sexual risk exposures. Overall, we could show that privacy concerns (hypothesis H2) and self-administered questionnaires (H3) were the strongest obstacles for complete disclosure of sexual risks in our study population whereas improved donor education (H1) and computer-assisted questionnaires (H4) may have limited impact in our donor population.

Additionally, we could clearly confirm that questions which did not ask for certain risk exposures but leave the risk assessment to donors are not always suitable to identify risk exposures. Asking for sex with frequently changing partners led to significantly higher non-compliance than asking for more than three sexual partners in the last year like it is done in the uniform DHQ. We therefore renew the recommendation to revise questionnaires where appropriate and to use clear questions only and avoid scope for interpretation [1, 44, 45].

Our study gives indications to possible limitations in donors' willingness to provide further detailed informa-

tion about sexual risk behaviour. Although we performed an anonymous survey, every fifth participant did not answer a question about condom use. Surprisingly, young donors aged 18–24 years were less open to answer questions about sexual behaviour than expected – every seventh donor in this group has withheld information about condom use. This is important in view of the current scientific as well as social discussion about the limits of population-based risk assessment for donor selection and the request for implementation of strategies that focus on fair appraisal of individual risks [46–50]. (I) A substantial reluctance towards expansion to detailed individual risk recording has to be kept in mind – even in young donors that may have risk exposures due to (higher) sexual activity. This may result in increased non-compliance as it was shown in a study that had evaluated a standardized European DHQ: potential donors have stated that they would answer more detailed questions about sexual risk (e.g., sexual behaviour of partners) less honestly compared to other health questions [40]. (II) As described for other countries, a gender-neutral policy may probably lead to broader exclusion of eligible low-risk donors [51, 52] and to lapsing of young (male) donors [53]. In our study, potential donor deferral due to a new sexual partner within 4 months before donation was substantially higher than in former studies that have evaluated a draft uniform questionnaire in Germany (4.8% vs. 0.9%, resp., 2.4%) [1, 54]. In our study, about 10% of donors younger than 35 years reported a new sexual partner within 4 months prior to donation and about 4% in this group had condom-less sex with a new partner. Deferral of donors with these risk exposures would lead to loss of approximately 280,000 donations (new partner, last 4 months) or 100,000 donations (condom-less sex, new partner) per year in Germany with potential further lapsing of young donors and related future deficiencies in blood supply. Therefore, introduction of gender-blind eligibility criteria should be discussed carefully. This approach has been evaluated internationally and has led to recent changes in donor selection criteria in the UK and France [55, 56]. Experience from these countries may provide further insights into modified selection policies. So far, the assessment of sexual infection risks in a questionnaire or interview has been deemed necessary in order to balance safety, sufficiency, and fairness in the donation process. To refrain from donor selection on the basis of reported sex behaviour altogether and to rely on self-deferral and testing would solve the problems of discomfort of candidate donors and non-compliance with these questions, but it would inevitably result in a higher risk of transfusion-transmitted infections [57]. Even though the rise in residual risk cannot exactly be determined, and will most likely remain very low, this is currently not under consideration.

Our study is subject to limitations in particular because response was lower than planned. However, the number of participants was large enough to detect non-compliance of MSM with the targeted statistical power as observed non-compliance was lower than expected.

Bias may have been introduced by differences in motivation of donors to participate. As we found lower response rates for larger BE with mobile teams or branches, we could not exclude an underrepresentation of certain donor groups that prefer to donate in such BE. However, although age distribution of invited donors from different BE varied substantially, we did not find substantial differences between invited and participating donor population regarding age and sex distribution. Furthermore, we have controlled our analyses for a probable impact of kind of donation site to minimize the impact of different recruiting strategies.

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Statement of Ethics

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.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

K.P. organized the study, analysed the data, and drafted the manuscript. S.A. customized the online survey and edited the paper. R.O. initiated and designed the study and edited the paper.

Data Availability Statement

The data set underlying the findings is available from the Zenodo repository (<https://doi.org/10.5281/zenodo.6394047>).

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