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Factors influencing confidential unit exclusions in blood donors

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Vox Sanguinis

Background and Objective In many countries blood donors can exclude their donated blood from being transfused in a confidential unit exclusion (CUE) process. We aimed to identify characteristics which might influence the decision for CUE.

Study Design and Methods In a 3-step approach we first enroled 29 German blood donation centers in 2005 and addressed how the clarity of different CUE forms applied in these centers was rated by first time blood donors and also assessed three newly designed CUE forms. Second, we performed a survey on the characteristics of the CUE process including 25 centers. Third, we performed an intervention study, in which the CUE form originally applied in the study centre was compared with a newly developed CUE form in a before-after study design with respect to the corresponding CUE rates.

Results (1) Clarity of the CUE forms varied considerably. (2) The CUE rate was higher ($P < 0{\cdot}05$) when nurses rather than a physician were involved in informing the donors and when the CUE form was submitted anonymously instead of being handed to a person. (3) Application of the newly designed CUE form which was rated as being very clear resulted in a 31% decrease in the CUE rate.

Conclusions Design of the CUE form and characteristics of the CUE process may considerably influence the CUE rates.

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Introduction

Transfusion medicine practices have achieved a tremendous reduction in the risk of pathogen transmission by blood products. This is the result of careful donor selection, exclusion of risk groups, improved methods of screening for pathogens, especially viruses, and the introduction of pathogen inactivation procedures. However, there is still a diagnostic window for hepatitis B, hepatitis C and human immunodeficiency virus (HIV), i.e. there is a time in which the virus can be transmitted by the donor's blood product while all laboratory tests on the donor's blood remain negative. Furthermore, there might be additional or emerging pathogens which are acquired by risk behaviour for which blood donors are not tested. The only way to recognize donors being at risk during this diagnostic window period is by a careful medical history. However, many high risk situations leading to an increased risk for infection with hepatitis or HIV are within the context of sexual behaviour. Therefore, blood donors might be in a compromising situation at the time of blood donation, which might prevent them from giving the information about high-risk activity, especially if they are accompanied by family members or friends to the donation clinic. A possible solution to this problem is the confidential unit exclusion (CUE). In CUE each donor is given the possibility to declare confidentially whether his or her donation is to be used for transfusion [1]. By means of this procedure every donor can withdraw

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his or her donation without any of the accompanying persons noticing it.

Confidential unit exclusion is used in several countries, as for example the United Kingdom, Switzerland, Iran, USA and Germany. However, there is little information published on the details of the procedures. In the German blood donation system which consists of several Red Cross blood donation services, independent hospital-based transfusion centers as well as private transfusion services; the CUE is regulated by the National Hemotherapy Guidelines. These guidelines require that all donors are screened by a written questionnaire and that detailed information about the donor's health status and about relevant pre-existing diseases is gathered via direct oral questioning. In the Greifswald transfusion medicine department, every blood donor is seen by a physician in private. Family members or friends are not allowed during physical examination and physician talk. The questionnaire is filled out in public at the waiting room and therefore confidentiality cannot always be secured. Since 1988 CUE is also mandatory [2]. However, the CUE process, including the CUE form, is not predefined in detail. The CUE can be explained to the donor by a physician, a nurse or support staff; the declaration concerning CUE can be recorded using the obligatory health questionnaire or using an extra CUE form for which there is no standard; and the procedure for gathering the CUE form can differ between centers, i.e. the CUE form can be returned to a person or it can be placed anonymously into a poll box. Hence, the question concerning the optimal CUE process arises. In the Greifswald transfusion medicine department, the CUE was filled in by the donor in privacy at the end of the donation process and then deposed into a poll box. Thus the donation process is independent of what the donor finally chooses to indicate on the CUE form.

There are already several studies addressing the effects of CUE. Most of these studies are not concerned with differences between different CUE processes, but with the quality of a specific CUE process or a specific group of these processes. In most of these studies laboratory parameters of persons with CUE are compared with parameters of persons without CUE [3–12]. In some of them the prevalence of markers for infectious disease in blood donors without CUE were at least slightly less frequent than in those with CUE [3–8,10]; the other studies showed no significant differences [9,11,12]. Only one study addressed the extent to which donors understood the CUE form [13]. This study revealed that donors with CUE to a significantly greater rate did not understand the CUE form compared with donors without CUE. Also only one study aimed at comparing different CUE processes [14]. This study revealed that demanding the declaration at the time of donation was better than only giving the opportunity of withdrawing the donation afterwards by a letter of recall.

We addressed the impact of different characteristics of the CUE process on CUE rates by a 3-step approach. First, we investigated how first time blood donors judged the clarity of the CUE forms applied in the different blood donations centers in Germany as well as of three newly developed CUE forms. Second, we performed a survey enrolling different German blood donation centers to identify aspects of the CUE process which may affect the CUE rates. Third, we compared in an intervention study at the blood donation centre Greifswald, whether changing the CUE form to a version which had been rated as very clear by first time blood donors (in study one), reduces the CUE rate.

Study 1: Clarity Rating of the CUE Forms

Material and methods

Material

In preparation of the study concerning the clarity of the CUE forms applied in the different German blood donor centers, all 80 German blood donor centers were asked by e-mail to send copies of their CUE forms to the study centre. A second request was not performed because those who did not respond were assumed to be not willing to participate and further insistence seemed to be inadequate. Beside the study centre (Department of Transfusion Medicine, Greifswald, Germany), 29 centers participated, of which one had to be excluded as this centre used a computer-based CUE process. Hence, 29 centers (36% of 80) were included. The CUE forms of these 29 centers constituted the main part of the material rated in this study 1. In addition, three newly designed CUE forms were investigated. The latter three forms were developed on the basis of the feedback given by donors of the study center, who had excluded their blood from transfusion by CUE. Most of these donors expressed that they had erroneously performed CUE and that the old form was confusing especially because of an overload of information. Therefore, two of the new forms contained essentially less information than the old form.

Study participants

Participants were first time blood donors, i.e. blood donors who were not familiar with any CUE forms. Furthermore, participants had to be native German language speakers. After standard pre-donation physical examination by a physician and explaination of the concept of CUE, these first time donors were asked to participate in the study. All 30 approached first time donors (15 males, 15 females) gave informed consent and participated (participation rate 100%). The mean age was 32·7 years (median 30·5 years, range: 19–57 years).

Procedure

The study participants received all 32 CUE forms and were asked to rate the clarity of these forms using a categorical scale with the categories 'very clear', 'clear' and 'not clear' in regard to whether the donated blood should or should not be transfused to patients. Each participant had as much time as he or she needed. Additionally, each CUE form was classified by study team according to five different formal characteristics, i.e. (1) format with the three categories 'DIN A4' (German paper size similar to US 'letter' format), 'DIN A5' (=1/2 DIN A4) and 'atypical format', (2) colour of writing with the two categories 'black on a plain sheet of paper' and 'coloured', i.e. red and/or green boxes to mark with a cross, (3) modes of printing with the two categories 'only on one side' and 'on both sides', (4) amount of text with the two categories 'much text, description of risk situations' and 'little text, without description of risk situations' and (5) use of icons with the two categories 'icons' and 'no icons'.

Statistical analyses

The differences between the 32 CUE forms were analysed via Friedman's rank analysis. Moreover, for each CUE form two different statistics were computed: (1) the median of the ratings given by the 30 study participants and (2) and the mean rank with respect to these ratings. To explore which formal characteristics of the CUE forms might influence the clarity, cross-tables between the clarity medians and the five different formal characteristics were constructed. Additionally, the relationships between the medians and the formal characteristics were tested statistically using Fisher's exact test. To control the false-positive error rate associated with performing multiple statistical tests the Bonferroni–Holm procedure was applied [15].

Results

The 32 CUE forms differed highly significantly ($P < 0{\cdot}001$) with respect to the clarity ratings. Of the 29 forms which were actually applied in routine blood donation, seven had a median rating of 'very clear', 18 a median rating of 'clear', three a median rating between 'clear' and 'not clear and one a median rating of 'not clear'. The median rating for all three newly developed forms was 'very clear' (see Table 1). Moreover, one of the three newly developed forms had the best mean rank of all 32 rated forms. For format and colour of writing (see Table 1) there was a significant relation ($P < 0{\cdot}05$) between formal characteristics and clarity. For 'standard paper size' (format) the clarity seemed to increase with the use of DIN A5 and for 'colour of writing' the clarity seemed to increase with using colours e.g. red or green instead of all black (see Table 1).

Table 1 Median clarity ratings and their relation with formal characteristics of the confidential self exclusion forms (study 1)

	Median rating[a]				
	Very clear	Clear	Between 'clear' and 'not clear'	Not clear	P^b
Total number	10[c]	18	3	1	
Format					
DIN A4	1 (10·0%)	14 (77·8%)	1 (33·3%)	1 (100·0%)	<0·001
DIN A5	7 (70·0%)	4 (22·2%)	0 (0·0%)	0 (0·0%)	
Atypical	2 (20·0%)	0 (0·0%)	2 (66·7%)	0 (0·0%)	
Colour of writing					
Black	2 (20·0%)	17 (94·4%)	2 (66·7%)	1 (100·0%)	<0·001
Coloured	8 (80·0%)	1 (5·6%)	1 (33·3%)	0 (0·0%)	
Modes of printing					
One side	8 (80·0%)	14 (77·8%)	0 (0·0%)	1 (100·0%)	0·052
Both sides	2 (20·0%)	4 (22·2%)	3 (100·0%)	0 (0·0%)	
Amount of text					
Much	8 (80·0%)	17 (94·4%)	3 (100·0%)	1 (100·0%)	0·527
Little	2 (20·0%)	1 (5·6%)	0 (0·0%)	0 (0·0%)	
Use of symbols					
Yes	7 (70·0%)	0 (0·0%)	0 (0·0%)	0 (0·0%)	0·068
No	3 (30·0%)	18 (100·0%)	3 (100·0%)	1 (100·0%)	

CUE, confidential unit exclusion.

[a]In brackets column per cent, i.e. per cent within CUE form with the same median clarity rating.

[b]*P*-value for Fisher's exact test for independence of rows and columns.

[c]Includes all three CUE forms newly developed in Greifswald.

Study 2: Survey of the German Blood Donation Centers

Material and methods

Material

For the main survey a questionnaire consisting of two parts was applied. The first section of this questionnaire was designed to gather information about the number of blood donations in each center and the number of discarded blood donations because of CUE, both during the calendar year 2005. The second section of the questionnaire contained questions concerning the persons who informed the donor about the CUE, and the manner in which the donor returned the CUE form. Three questions were relevant in this context. The first question addressed the person who informed the primary donors. Four answer possibilities were given: (1) 'support staff', (2) 'nurse', (3) 'physician' and (4) free text. Multiple answers were allowed. The second question addressed the person who informed the follow-up donors and was combined with the same answer modalities as the first question. The third question addressed the manner in which the CUE form was returned. The answer possibilities

were (1) 'into a poll box', (2) 'returned to the physician', (3) 'returned to the support staff or the nurse' and (4) free text.

Participants and procedure

The questionnaire was sent to those 28 centers which had provided their CUE forms for the first study. It was completed either by the director of the blood donation service or a person authorized by the director. Center data were included in the statistical analysis on number of donations and on number of CUEs in the year 2005.

Statistical analyses

The statistical analyses were concerned with five potential determinants of the CUE rate: (1) the clarity of the CUE form, (2) the extent to which a physician was involved in informing the donor, (3) the extent to which a nurse was involved in informing the donor, (4) the extent to which support staff was involved in informing the donor and (5) the manner of returning the CUE form. The first variable was constructed via the medians of the clarity ratings obtained in the first study. The three variables concerning the involvement of the three different professional groups were constructed by aggregating the answers to the two questions about the person informing the donor. From these answers a single index for each of the three professional groups was build. This index could take on three different values. An index value of zero was assigned when the respective group was not at all involved in informing the donors, an index value of one was assigned when this group was involved in informing either the primary or the follow-up donors, and an index value of two was assigned when this group was involved in informing both the primary and the follow-up donors. The fifth variable was constructed from the answers to the question addressing the manner of returning the CUE form. These answers were condensed into the two categories 'returning in a poll box' and 'handing to a person'.

Several descriptive statistics were computed which all refer to the five variables just described. At first, for each category of these variables the number and percentage of donation centers as well as the number and percentage of donations for which the respective category was realized were computed. For example, for the variable 'manner of returning the CUE form' the numbers and percentages of those donation centers in which the CUE form was handed to a person was determined. The same was carried out for those donation centers in which the CUE form was deposited into a poll box. Moreover, for both cases, the numbers and percentages of donations represented by the corresponding centers were calculated. Subsequently, mean, SD, minimum and maximum of the center-specific CUE rates were determined within each category of each of the five variables.

For investigating the effect of the determinants on CUE rates a logistic two-level random intercept model [16] with donations as lower and donation centers as higher level was applied. The five potential determinants were applied as predictors and CUE as criterion. The medians of the clarity ratings as well as the different ways of returning the CUE form were entered in dummy coding, the indices of involvement in informing the donors in the coding are described above. Statistical tests and computations of confidence intervals were performed according to the population average model.

Results

Of the 28 blood donation services approached for participation in the study, 18 donation centers responded immediately, seven donation centers responded after the second request, two donation centers responded after the third request. One center did not respond. Three of the responding 27 donation centers had to be excluded. Two of these three donation centers collected only platelet apheresis donations, and one donation center communicated no absolute numbers of the donors and the CUEs. Including the study center the sample comprised 25 centers at which a total of ~2·9 million blood donations were collected per year. These donations represented about two-thirds of all blood donations in Germany in the year 2005 (4·6 million) [17].

Within the included 25 centers the median ratings concerning the clarity of the CUE forms were 'very clear' for 7, 'clear' for 16 and between 'clear' and 'not clear' for 2. Correspondingly, only the three categories 'very clear', 'clear' and 'between 'clear' and 'not clear' were applied as categories within the multivariate analysis. Thereby, the last category was taken as reference category and odds ratios were estimated for the first two categories.

The CUE rates varied between 0·00% and 0·78% with a mean of 0·26%. In the multivariate analysis referring to these CUE rates 2 of all 6 tests yielded a significant result ($P < 0·05$): (1) the CUE rate was higher when nurses or support staff rather than a physician were involved in informing the donor and (2) the CUE rate was higher when the unit exclusion form was deposed anonymously into a poll box instead of being handed to a person (see Table 2).

Study 3: Intervention Study in Greifswald

Materials and methods

Material

In the intervention study two CUE forms were compared. One of these was the CUE form which was originally applied at the study center (Fig. 1); the other (Fig. 2) was

Table 2 Results of the survey on the characteristics of the confidential self exclusion process in 25 German blood donation centers (study 2)

	Absolute numbers and percentages per category[a]		Center-specific CUE rates				
Categories	Donations[b]	Donation centers[c]	Mean	SD	Minimum	Maximum	Odds ratio[d]
Clarity rating							
Very clear	1902435 (65·5)	7 (28·0)	0·30	0·24	0·07	0·78	0·97 (0·32–2·96)
Clear	728738 (25·1)	16 (64·0)	0·21	0·15	0·00	0·63	0·65 (0·23–1·88)
Between 'clear' and 'not clear'	272990 (9·4)	2 (8·0)	0·52	0·31	0·30	0·74	1·00 (reference)
Involvement of physician in donor information							
Not at all	13840 (0·5)	1 (4·0)	0·74	–	0·74	0·74	
Only primary donors	120644 (4·2)	8 (32·0)	0·35	0·23	0·17	0·78	**0·53*** (0·31–0·91)[e]
Primary and follow-up donors	2769679 (95·4)	16 (64·0)	0·18	0·12	0·00	0·43	
Involvement of nurse in donor information							
Not at all	857829 (29·5)	10 (40·0)	0·17	0·10	0·00	0·30	
Only primary donors	10679 (0·4)	1 (4·0)	0·18	–	0·18	0·18	1·05 (0·74–1·50)[e]
Primary and follow-up donors	2035655 (70·1)	14 (56·0)	0·33	0·24	0·07	0·78	
Involvement of support staff in donor information							
Not at all	1904178 (65·6)	20 (80·0)	0·27	0·19	0·07	0·78	
Only primary donors	6286 (0·2)	1 (4·0)	0·00	–	0·00	0·00	1·01 (0·67–1·53)[e]
Primary and follow-up donors	993699 (34·2)	4 (16·0)	0·26	0·27	0·04	0·63	
Manner of returning the CUE form							
Placing form into a poll box	2873947 (99·0)	22 (88·0)	0·28	0·20	0·07	0·78	**3·48*** (1·15–10·52)
Handing form to a person	30216 (1·0)	3 (12·0)	0·08	0·11	0·00	0·21	1·00 (reference)

CUE, confidential unit exclusion, statistically significant differences are given in bold.

[a]Percentages in brackets.

[b]n = 2904163.

[c]n = 25.

[d]Estimated and tested with a logistic two-level random-intercept model (population-average); bivariate analyses.

*P < 0·05; in brackets 95% confidence interval.

[e]Refers to the coding 0 = 'not at all', 1 = 'only primary donors', 2 = 'primary and follow-up donors'.

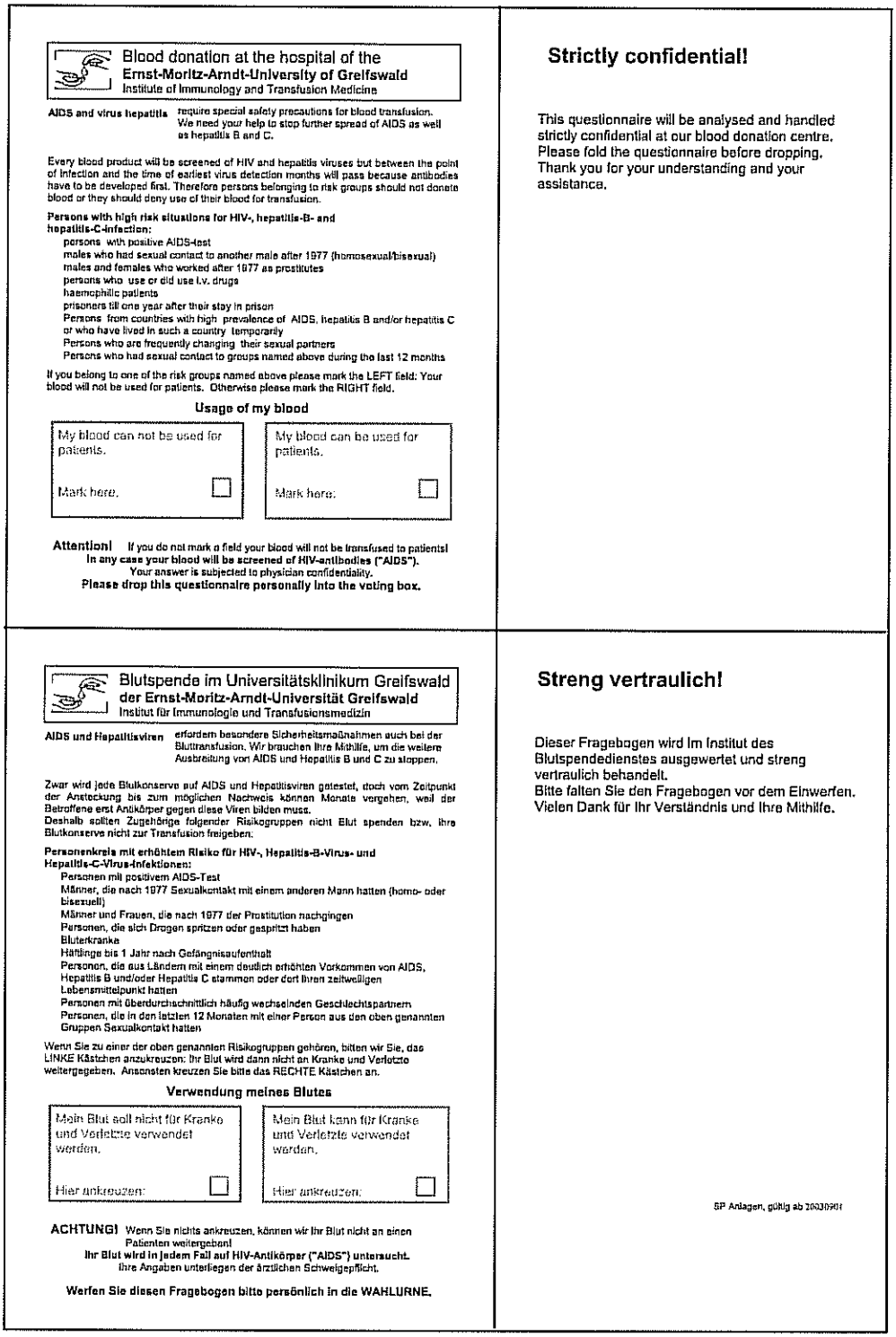
one of the three newly developed CUE forms for which the clarity rating described above was performed. This newly developed CUE form had achieved the best clarity ratings by first time donors (see above). This CUE form was designed using DIN A5 white paper with black large font lettering, red and green coloured boxes for yes and no [my blood can/should not be used for patients] and self-explaining pictograms. It is minimally worded and does not include specific mentioning of risk situations for HIV, hepatitis B and hepatitis C infections. These risk situations are listed in detail (see Table 3) on the pre-donation questionnaire each donor had to complete and sign before blood donation. Also, we chose a one-sided instead of a two-sided form because readers might forget the first part of the message if they had to turn the page in the middle of the message [18].

Participants and procedure

The study was performed as a before-after study. The old form was applied from January 2006 to April 2007 (16 months), the new from May 2007 to June 2008 (14 months). During these periods all consecutive donors were enroled. Over the entire study period all other mandatory standard operation procedures of handling the CUE remained the same. This included the verbal explanation to first time donors of the CUE, namely, by a physician before donation and by a nurse to all donors during donation, and the manner of returning the CUE form into a poll box after donation.

Statistical analyses

To investigate the effect of the new CUE form the CUE rate from January 2006 to April 2007 was compared with the



Blood donation at the hospital of the
Ernst-Moritz-Arndt-University of Greifswald
Institute of Immunology and Transfusion Medicine

AIDS and virus hepatitis require special safety precautions for blood transfusion. We need your help to stop further spread of AIDS as well as hepatitis B and C.

Every blood product will be screened of HIV and hepatitis viruses but between the point of infection and the time of earliest virus detection months will pass because antibodies have to be developed first. Therefore persons belonging to risk groups should not donate blood or they should deny use of their blood for transfusion.

Persons with high risk situations for HIV-, hepatitis-B- and hepatitis-C-infection:

- persons with positive AIDS-test
- males who had sexual contact to another male after 1977 (homosexual/bisexual)
- males and females who worked after 1977 as prostitutes
- persons who use or did use i.v. drugs
- haemophilic patients
- prisoners till one year after their stay in prison
- Persons from countries with high prevalence of AIDS, hepatitis B and/or hepatitis C or who have lived in such a country temporarily
- Persons who are frequently changing their sexual partners
- Persons who had sexual contact to groups named above during the last 12 months

If you belong to one of the risk groups named above please mark the LEFT field: Your blood will not be used for patients. Otherwise please mark the RIGHT field.

Usage of my blood

My blood can not be used for patients. Mark here. ☐	My blood can be used for patients. Mark here. ☐

Attention! If you do not mark a field your blood will not be transfused to patients!
In any case your blood will be screened of HIV-antibodies ("AIDS").
Your answer is subjected to physician confidentiality.
Please drop this questionnaire personally into the voting box.

Strictly confidential!

This questionnaire will be analysed and handled strictly confidential at our blood donation centre. Please fold the questionnaire before dropping. Thank you for your understanding and your assistance.

Blutspende im Universitätsklinikum Greifswald
der Ernst-Moritz-Arndt-Universität Greifswald
Institut für Immunologie und Transfusionsmedizin

AIDS und Hepatitisviren erfordern besondere Sicherheitsmaßnahmen auch bei der Bluttransfusion. Wir brauchen Ihre Mithilfe, um die weitere Ausbreitung von AIDS und Hepatitis B und C zu stoppen.

Zwar wird jede Blutkonserve auf AIDS und Hepatitisviren getestet, doch vom Zeitpunkt der Ansteckung bis zum möglichen Nachweis können Monate vergehen, weil der Betroffene erst Antikörper gegen diese Viren bilden muss.
Deshalb sollten Zugehörige folgender Risikogruppen nicht Blut spenden bzw. ihre Blutkonserve nicht zur Transfusion freigeben:

Personenkreis mit erhöhtem Risiko für HIV-, Hepatitis-B-Virus- und Hepatitis-C-Virus-Infektionen:

- Personen mit positivem AIDS-Test
- Männer, die nach 1977 Sexualkontakt mit einem anderen Mann hatten (homo- oder bisexuell)
- Männer und Frauen, die nach 1977 der Prostitution nachgingen
- Personen, die sich Drogen spritzen oder gespritzt haben
- Bluterkranke
- Häftlinge bis 1 Jahr nach Gefängnisaufenthalt
- Personen, die aus Ländern mit einem deutlich erhöhten Vorkommen von AIDS, Hepatitis B und/oder Hepatitis C stammen oder dort ihren zeitweiligen Lebensmittelpunkt hatten
- Personen mit überdurchschnittlich häufig wechselnden Geschlechtspartnern
- Personen, die in den letzten 12 Monaten mit einer Person aus den oben genannten Gruppen Sexualkontakt hatten

Wenn Sie zu einer der oben genannten Risikogruppen gehören, bitten wir Sie, das LINKE Kästchen anzukreuzen: Ihr Blut wird dann nicht an Kranke und Verletzte weitergegeben. Ansonsten kreuzen Sie bitte das RECHTE Kästchen an.

Verwendung meines Blutes

Mein Blut soll nicht für Kranke und Verletzte verwendet werden. Hier ankreuzen: ☐	Mein Blut kann für Kranke und Verletzte verwendet werden. Hier ankreuzen: ☐

ACHTUNG! Wenn Sie nichts ankreuzen, können wir Ihr Blut nicht an einen Patienten weitergeben!
Ihr Blut wird in jedem Fall auf HIV-Antikörper ("AIDS") untersucht.
Ihre Angaben unterliegen der ärztlichen Schweigepflicht.

Werfen Sie diesen Fragebogen bitte persönlich in die WAHLURNE.

Streng vertraulich!

Dieser Fragebogen wird im Institut des Blutspendedienstes ausgewertet und streng vertraulich behandelt.
Bitte falten Sie den Fragebogen vor dem Einwerfen.
Vielen Dank für Ihr Verständnis und Ihre Mithilfe.

SP Anlagen, gültig ab 20030901

Fig. 1 Confidential unit exclusion (CUE) form used at the blood donation center Greifswald until April 2007, paper size format DIN A5, printed on both sides. The upper panel shows the English translation, the lower panel shows the original German form.

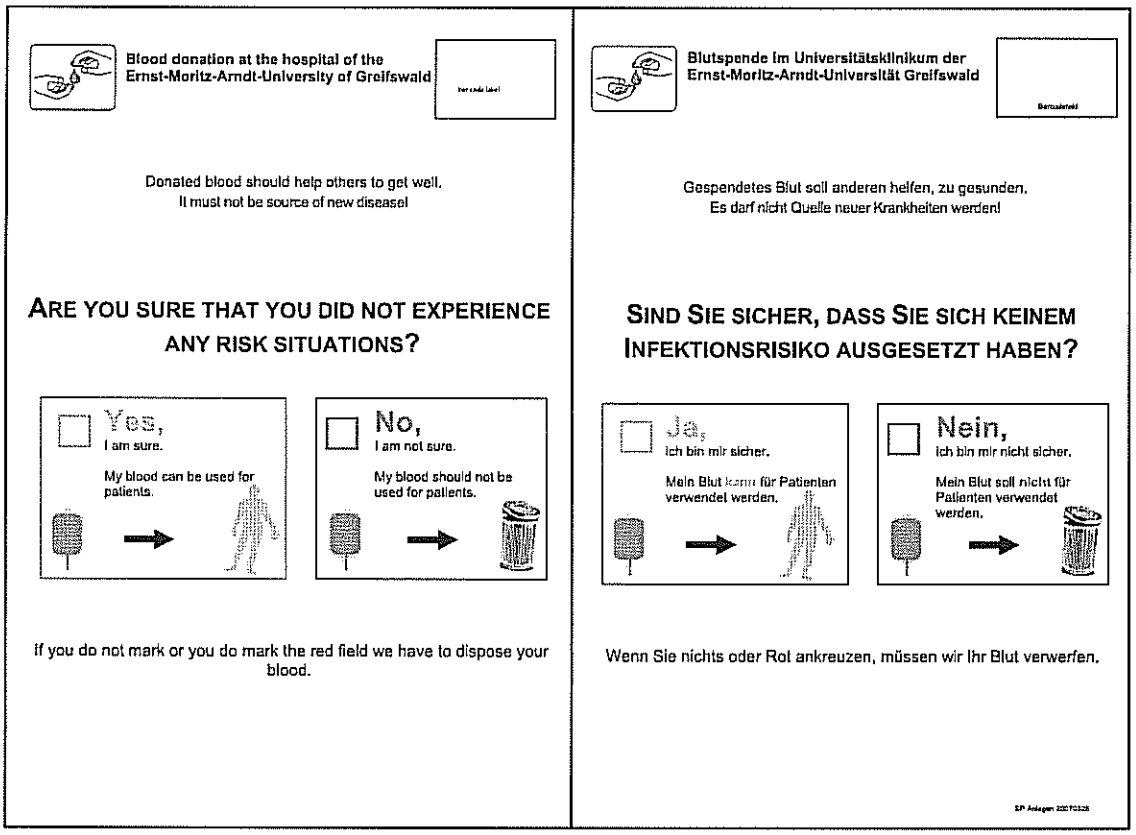


Fig. 2 Newly created confidential unit exclusion (CUE) form in Greifswald since May 2007, paper size format DIN A5; printed on one side. The left panel shows the English translation, the right panel shows the original German form.

rate from May 2007 to June 2008 by means of a Chi-squared test.

Results

The CUE rate decreased essentially when the new CUE form was introduced. When the original CUE form was applied, i.e. in the time from January 2006 to April 2007, the CUE rate was 0·66% (188 CUEs in 28457 blood donations). In contrast, when the new CUE form was applied, i.e. in the time from May 2007 to June 2008, the CUE rate was only 0·45% (117 CUEs in 26157 blood donations; $P < 0·001$). In neither study period, any of the donations excluded by the CUE process tested positive in any of the screening tests applied (HIV 1 and 2, hepatitis C virus, treponema pallidum antibodies, hepatitis B antigen, nucleic acid testing for HIV and hepatitis C).

Discussion

The three inter-related studies presented here showed an effect of the design of the CUE form on the rate of self-excluded blood donations and implied that the characteristics of the CUE process probably also had an impact. In particular we showed that using a CUE form which was regarded as very clear by first time blood donors could reduce the CUE rate by more than 30%. Neither of the studies was a randomized controlled trial. However, with the variables considered here, genuine randomized controlled trials are very difficult to perform and, actually, have not been performed yet. In this respect, the survey on the CUE process and the before-after intervention study corresponded to the best methodological standard which has up to now been realized within this context. The 25 blood donation centers which were eligible for the statistical analyses, accounted for nearly 3 million blood donations per year in Germany and therefore reflected the majority of the 4·6 million annual blood donations in the country. Furthermore, because the statistical analyses focused on relationships between variables and not on univariate statistics, as for example means or medians, a serious bias was unlikely. Our study has a major advantage due to the diversity of the German blood donation system, with many different blood donation services, which all used slightly

Table 3 Information given in the questionnaire which each donor has to fill out and sign before blood donation: persons with high risk situations for HIV, hepatitis B and hepatitis C infection

Persons with positive AIDS test
Males who had sexual contact with another male after 1977 (homosexual/bisexual)
Males and females who worked after 1977 as prostitutes
Persons who use or did use i.v. drugs
Haemophilia patients
Prisoners till 1 year after their stay in prison
Persons from countries with high prevalence of AIDS, hepatitis B and/or hepatitis C or who have lived in such a country temporarily
Persons who are frequently changing their sexual partners
Persons who had sexual contact to groups named above during the last 4 months

HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome.

different processes; it is likely that the findings of the present study can also be applied to other countries.

Our study suggests that small changes in the CUE process may have considerable impact on the CUE rates. The CUE rates in the different blood donation services varied between 0·00% and 0·78% with a mean of 0·26%. Although this appeared as a small difference only, a 0·5% difference in CUEs accounted for more than 20000 blood donations per year in the country. We found three factors related to the process of CUE which significantly influenced the CUE rate. The survey helped to identify:

1) the extent to which a physician was involved in informing the donors about the CUE;
2) The manner in which the CUE form was returned, i.e. handed directly to a person rather than deposited anonymously into a poll box; and
3) the intervention study in Greifswald revealed that the design of the CUE form by itself also had an impact on CUE rates

The impact of the physicians' involvement in informing the donors on the CUE rate might be explained in several different ways. One kind of explanation refers to differences between the physicians and the other professional groups with respect to informing the donors. For example, the physicians might, because of a larger background knowledge, give clearer explanations than members of the other professional groups. A different kind of explanation refers to factors which are associated with the way in which the different professional groups are integrated into the donation process. For example, physicians usually talk to the donors in private whereas members of the other professional groups give their explanations in public. This, in turn, might have the effect that donors listened more attentively to the physician.

The impact of the manner of returning the CUE form on the CUE rate can also be explained in different ways. One explanation refers to the fact that people are more willing to admit socially undesired behaviour the more they feel that anonymity is guaranteed [19,20]. Accordingly, donors are more willing to admit risky behaviour when they return the CUE anonymously. This, in turn, produces an increase in the CUE rates. An alternative explanation for the effect might be that handing the form to a person induced the donors to think more carefully about their answer on the form when compared with deposing the form into a poll box. This, in turn, might reduce the number of erroneous declarations.

Also the effect that changing the CUE form at the blood donor center of Greifswald substantially decreased the CUE rate can be explained from different perspectives. Because the second CUE form received the best clarity ratings in the preliminary study, the nearest at hand explanation consists in attributing this effect to differences in clarity. However, also the first CUE form had a median rating of 'very clear', and in the survey of the different German donor centers no statistically significant relation between clarity and CUE rate was found. An alternative explanation refers to the fact that the two CUE forms in the intervention study differ not only with respect to their clarity but also with respect to other aspects. For example, in contrast to the new CUE form the old CUE form contains a list of those events because of which donors should withdraw their donation. This might make donors more sceptical against their donation. Still a different explanation might be that changing the CUE form and monitoring the CUE rates in a study was accompanied with the staff becoming more aware of the relevance of CUEs. This, in turn, might have decreased the CUE rates.

Of course, the CUE rates alone do not reflect the sensitivity and the specifity of the corresponding CUE processes. For this reason, they do not directly reflect the quality of these processes. A reduction of the CUE rate might be caused by a lower rate of false exclusions or by a higher rate of false inclusions, i.e. by a higher specificity or by a lower sensitivity, respectively. To check whether there is an improvement or a deterioration, a new study is required in which the quality of CUE and none-CUE donations and/or the validity of CUE and none-CUE donors' declarations is additionally assessed in both conditions to be compared. This, however, will require very large sample sizes due to the overall low prevalence of a CUE and the even lower prevalences of infectious markers. Considering the results presented here, such studies would be most promising for comparing (1) high physician's involvement in donor information with low physician's involvement and (2) anonymous returning of the CUE form with handing it to a person.

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